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IN SITU: Evaluation of the acceptability and the impact of in situ simulation in emergency medicine: a mixed method study

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IN SITU: Evaluation of the acceptability and the impact of in situ simulation in emergency medicine: a mixed method study

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Keywords: Simulation, in situ, emergency medicine, acceptability, feasibility, stress, satisfaction, burn out, professional wellbeing

Authors' contributions: JT led the development of the protocol and drafted the manuscript. VB ERD & MÉ drafted the manuscript with the first author. CM, EB, JM, GM, GC, CG & GB critically revised and approved the final version of the manuscript.

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ABSTRACT

Introduction:
In situ simulation (ISS) is simulation in the everyday working environment with usual team members. Our hypothesis is that in situ simulation in an academic high-volume emergency department is feasible, safe, and is associated with benefits for both staff and patients. Our main objective is to assess the feasibility, acceptability and the impact on participants stress of two types of ISS in the emergency department: announced (outside of the work shift) or unannounced (during the work shift).

Methods:
A mixed method including a qualitative method for the assessment of feasibility and acceptability and quantitative method for the assessment of safety, stress and skills of the participants will be used in this study.
Two distinct phases are planned in the emergency department of the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus: 1) Phase 1: Implementation of an ISS program with selected emergency professionals to assess acceptability, safety and prove the validity of our concept. The number of cancelled sessions and the reasons for cancellation will be collected in order to establish feasibility criteria. Semi-structured interviews will evaluate the acceptability of the intervention, 2) Phase 2: The impact of the ISS program will be measured with validated questionnaires for the assessment of self-confidence, psychosocial risks and perceived stress among non-selected emergency professionals.

Ethics and dissemination: Local institutional research ethics board has approved this protocol. Results will be presented to key professionals from our institution to improve patient safety. We also aim at publishing our results in peer-reviewed journals and will submit abstracts in international simulation-based education conferences in order to disseminate our findings.

Impact for Emergency Medicine:
The feasibility of ISS in emergency medicine has never been assessed before. ISS offers the possibility for pragmatic, regular simulation training in adequacy with specific local needs.

Keywords: Simulation, in situ, emergency medicine, acceptability, feasibility, stress, satisfaction, burn out, professional wellbeing

Strengths and limitations of this study:

- This study is the first to assess the acceptability, feasibility and safety of conducting in situ simulation in a busy academic emergency department
- The safety issue of ISS is an important ethical consideration, which is included in our research
- ISS offers the possibility of improving patient safety through training. The impact of ISS has been illustrated recently in a systematic review on the effect of ISS on patient outcome.[1]
- However, the scope of our results might be restrained by methodological limitations such as the absence of randomization and blinding of participants to the outcome.

INTRODUCTION

Simulation is an innovative teaching tool used for the acquisition and training of technical and non-technical skills.[2] Numerous studies have shown that simulation is associated with a significant beneficial effect for every health professional.[3, 4] Emergency medicine (EM) is a complex specialty that requires multiple technical and non-technical clinical skills and knowledge. Simulation allows the acquisition and retention of these specific skills that are necessary in order to manage everyday situations and other rare clinical cases. A wide variety of simulation aids exist, ranging from simple task manikin to virtual reality or hybrid simulation using live actors and manikins to increase realism.[5] The choice of the right tool must be based on a just balance between learning objectives and the required level of realism. Realism, also called fidelity in simulation,[6] greatly impacts the quality of learning and especially the transfer of these skills to the real clinical world.[7] However, educators must carefully examine the stress generated by the simulation exercise. Stress can limit skill acquisition if the exercise is too complex for the participant's qualification and previous experience.[8, 9]

Simulation training can take place in a dedicated center, often near the hospital or healthcare unit, which can limit its wide implementation. The costs of a simulation center are significant, mostly because of human resources and structural costs. The ED environment is also quite different from simulation centers, thus decreasing the realism of the training. It also has become increasingly difficult to recruit participants for specific and repeated training, especially when it is set to take place far from the usual working place and outside usual working hours.

In situ simulation (ISS), a type of simulation, integrated into the targeted clinical environment, is a pragmatic solution to these issues. The rationale is based on the importance of the environmental fidelity and its potential impact on learning.[10] Studies comparing the two environments in simulation are scarce. This could be due to the complex methodology required for their implementation.[11] Nevertheless, a 2015 randomized study highlighted that the participants' perception of realism was considerably higher in the in situ group.[11, 12] ISS also offers the interesting possibility of identifying the conditions that can lead to errors in the usual working environment. This allows a better anticipation of potential errors and therefore the possibility of reducing their incidence.[13] Numerous studies illustrate the positive impact of ISS on the practice of healthcare professionals from various specialties

including the demonstration of improved patient outcome.[14-17] However, the complex environment of an ED can add challenge for educators conducting ISS training. The difficult work conditions (overcrowding, task interruptions, understaffing) in emergency medicine can be a major practical limit to the implementation of ISS training.[18] However, the literature comparing different types of in situ simulation is still scant. Therefore, our novel study will aim to describe and compare the feasibility, acceptability and the impacts of two different types of in situ simulation in the emergency department: announced (outside the work shift) or unannounced (surprise simulation during the work shift).

We hypothesise that in situ simulation in an emergency department is feasible, safe and is associated with benefits for health professionals and for patients.

Objectives

Primary objective

To assess the feasibility, acceptability and participants stress of two types of ISS in the emergency department: announced (outside of the work shift) or unannounced (during the work shift).

Secondary objectives

1) To assess the patient safety of unannounced ISS

2) To assess and compare the psychosocial risks for the participants according to their exposure to ISS

3) To evaluate the satisfaction of the participants according to the exposure to ISS

4) To evaluate technical and non-technical skills during ISS for each participant

5) To evaluate the number of Latent Safety Threats (LST) identified during the training (13)

METHODS AND ANALYSIS

Study design and setting

We will conduct a two-phased mixed method study: qualitative for the assessment of feasibility and acceptability and quantitative for assessing the participants' safety, stress and skills.

The study will be conducted at the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus), a Canadian university-affiliated Level-1 trauma centre, with an annual census of 67000 visits. The ED resuscitation /trauma team is activated by the triage nurse by a voice announcement. In our study, the resuscitation/trauma team will be notified through the usual process with no mention of 'simulation' when the simulation is unannounced. Otherwise, the announced simulations will always take place in the same resuscitation/trauma area of the ED.

Population

ED health professionals from the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus) will participate to the ISS training. Teams of seven participants will be involved in each of the sessions (three nurses, two emergency physicians, a respiratory therapist and a resident). The emergency physicians are either Royal College emergency specialists (FRCP) (5-year training) or emergency trained family physician (3-year training) from the Canadian College of Family Physicians).

Participants will be included and benefit from the ISS training after informed oral consent is obtained.

Scenario design

Scenarios are inspired by real patients from a different ED in order to avoid participants from recognizing real cases, which may lead to increased stress and unsolicited cognitive load for some ED professionals. These scenarios will encompass common clinical presentations and will focus on two pathologies of interest for this ED, severe trauma (such as traumatic brain injury, penetrating thoracic trauma, massive transfusion protocol activation) and cardiac arrest.

The simulation team tested the scenarios beforehand during dedicated simulation training with a different population than the study participants. One of the key elements for designing this study was to answer and be in line with the local specific

teaching needs, and therefore to offer a pragmatic and useful training format that could easily translate into improved patient care. For these reasons, it was fundamental to use very realistic scenarios from prevalent clinical cases.

Simulations

For this study, we will use a Crash Kelly manikin from Laerdal (Laerdal Medical, Stavanger, Norway). As with other authors, we believe that the fidelity of the manikin itself is probably not that relevant to ensure learning,[19, 20] whereas the fidelity of the environment or of the scenario is probably more important in the learning process.[7, 10, 21] To enhance realism and ensure flow immersion,[22] we will also use a thoracic prototype created within our simulation lab for the scenarios requiring thoracic invasive intervention (insertion of chest tube, and/or thoracotomy).

We will use real medications, with the exception of opioids and blood derived products. If they are required for the simulation, the participants will be advised to use saline instead. Since the training will take place in the trauma resuscitation area, the research team has the responsibility of limiting the risks of mixing up real and false medication. This system will not only enhance realism but also maximize safety.[23]

The ISS trainings will be short, 30 minutes in total (15 minutes of simulation then 15 minutes of debriefing)[24] and will follow the classic briefing-simulation-debriefing plan.[25] Debriefing is essential to ensure effective learning, and will follow the PEARL guidelines to optimize the educational impact for all participants.[26]

Procedure

Phase 1 (figure 1)

In the first phase of our study, we will assess the feasibility, acceptability and safety of implementing announced or unannounced ISS during working shifts in a busy ED. Feasibility and acceptability will be assessed using semi-structured individual interviews.[27] Those interviews will cover topics based on our preestablished thematic framework (see online supplementary material). The number of cancelled sessions and the reasons for cancellation will also be collected to establish feasibility grids.

Safety is often an obstacle to ISS with working staff.[28] Quantitative parameters measuring the impact of these trainings on patient care will be collected: 1) the median wait time and 2) the number of patients who left without being seen. This

information will be extracted from the institution's ED software and the data pertaining to the day of the unannounced ISS will be compared to that of the 3 days preceding the ISS, stratified by working shifts (8-16h, 16-0h00, 0-8h). Dedicated research staff will be present in the ED during the simulations in order to record the occurrence of adverse events for patients (accident report) and the impact of the simulations on the working staff (understaffing).

Phase 2 (figure 2)

Unannounced ISS, meaning that it will take place during a work shift and the participants will not be previously informed of this ISS, will be widely implemented following phase 1. This second phase will focus on assessing the impacts of unannounced ISS on health professionals. The format and content of the ISS training will be drawn from the data collected during the first phase. We will assess the impact on stress, self-confidence and professional wellbeing using validated satisfaction and stress scales.[29-31] The state anxiety questionnaire will be used as well as the measurement of perceived stress,[30] both validated for this type of methodology. The psychosocial risk assessment questionnaire and the assessment of self-confidence will reflect general professional well-being with validated assessment tools from the literature.[32, 33] In a recent study, simulation training provided a significant decrease in work stress among nurses in an intensive care unit.[29] To demonstrate this benefit, the personnel exposed to the ISS training (intervention group) will be compared to those that were not exposed to ISS (control group) using the same questionnaires.

Outcomes:

Primary outcome:

Phase 1: Acceptability according to the two groups: announced / unannounced

Phase 2: Stress levels according to the two groups (control or intervention)

Secondary outcomes:

Quantitative safety parameters (wait times, adverse events, departures without being seen)

Comparison of self-confidence levels according to the two groups

Comparison of psychosocial risks according to the two groups

Number of risk of errors, LST and evaluation grid for technical and non-technical skills during ISS

Analyses

Thematic content analyses

Thematic content analysis will be performed for semi-structured interviews. A thematic analysis by constant comparison will make it possible to select and organize categories condensing the meaning of the interviews.[34, 35] Thematic analysis is based on coding, of which there are three levels: open, axial and selective coding. The analysis of the transcripts allows the creation of non-interpretative descriptive open codes. They are then classified and grouped into categories and subcategories: this is axial coding. Then the theory will be created via selective coding, by assembling the concepts to make a narrative: this is the modeling carried out using matrices. We will use NVivo12pro® software with double blind coding.

Quantitative analyses

The quantitative analyses will include comparisons between the different participating groups by paired t-tests, Wilcoxon signed-rank tests and chi-squared tests. Continuous data will be expressed as an average (standard deviation) when they are normally distributed and as a median [interquartile range Q1-Q3] otherwise. The categorical variables will be expressed in number (percentage). Categorical variables will be compared using the Chi-square test or the Fisher's exact test, if applicable. SAS® statistical software will be used for all statistical analysis.

Safety and ethical considerations

This study has been approved by the CHU de Québec-Université Laval Research ethics board. Potential participants to this study will receive an information formvia email and in person before the announced ISS training. This information form will be distributed to every emergency professional with a dedicated contact from the research team available for any question or if a person refuses to participate to the study. Oral consent will be obtained, and the participants will have the possibility of withdrawing at any moment of the study. The risks of participating in the study are no higher than when providing routine care to patients and/or during simulation training.

In order to ensure patient safety and limit the risks of disrupting patient care in the ED during ISS, the simulation experts have designed specific "go/no go" criteria. Among those criteria (significant workflow, understaffing, equipment and bed availability on wards) if a real trauma patient is expected or ongoing, the ISS will be cancelled, and the simulation team will leave the trauma room in the same state as it was upon arrival.

Limitations

Our study has some methodological limitations, most of them inherent to simulation studies.

ISS is new to the study site's ED and therefore to improve adherence from the professionals, we have limited the number of announced and unannounced simulation to 8 each. After phase 1, we will adapt the number of ISS to the results obtained from our qualitative analysis.

We accepted the selection bias created by the selection of champions during phase 1. The aim being the validation of our concept, the recruitment of motivated volunteers from the ED staff seemed to be an acceptable limit to the generalization of our results. However, identifying and preparing champions is a widely accepted practice and is also recommended by experts in change implementation.[36]

For obvious reasons, randomizing participants would not have been ethically acceptable. It was also impossible to blind participants to the outcomes of the study, because the information form indicated they would have to fill out questionnaires and undergo semi-directed interviews. However, the analysis and group comparisons will respect the allocation blinding.

It was difficult to find the optimal compromise between short, pragmatic and acceptable ISS training to limit the risks to the functioning of the ED while ensuring effective learning and maintaining educational objectives.

For these reasons, we opted for "quieter" moments of the day and therefore were not able to reproduce the realism and inherent chaos from the ED.

Expected benefits and originality

This is the first scientific work to assess the feasibility and impact of implementing ISS training in emergency medicine. It is therefore an original, unexplored training

situation associated to a practical impact. ISS is a pragmatic and safe teaching method, in line with the specific constraints and needs pertaining to emergency medicine. In addition, one of the main limits to the wide implementation of simulation is its high cost. If ISS proves acceptable and feasible in the ED, it could reduce the costs inherent to the structure (simulation center) and associated human resources, while increasing the safety of care. The impact of these trainings on patient care will be measured through simple epidemiologic data collection. Improved care for severe trauma patients would also translate into lower public health costs. In addition, few studies exist on the importance of realism in simulation, but the importance of training in conditions close to real practice has already been shown.[21]

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FIGURES

Figure 1. Phase 1

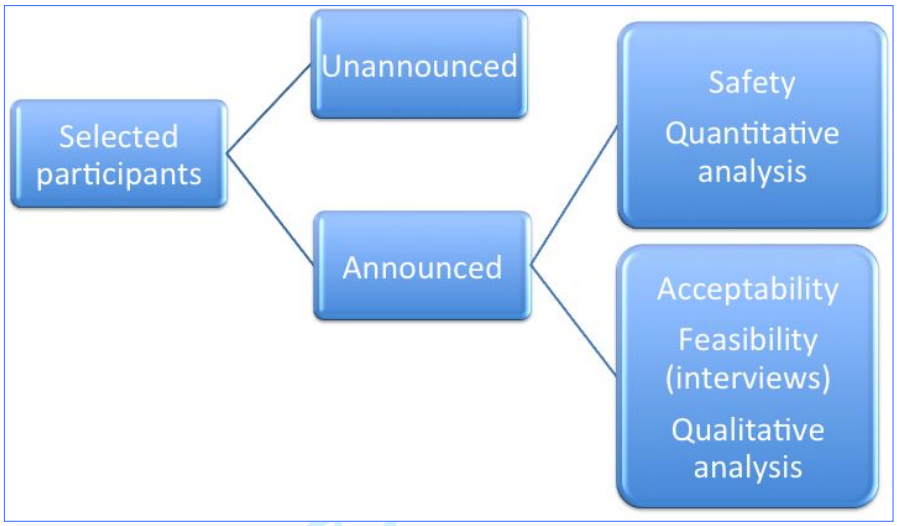
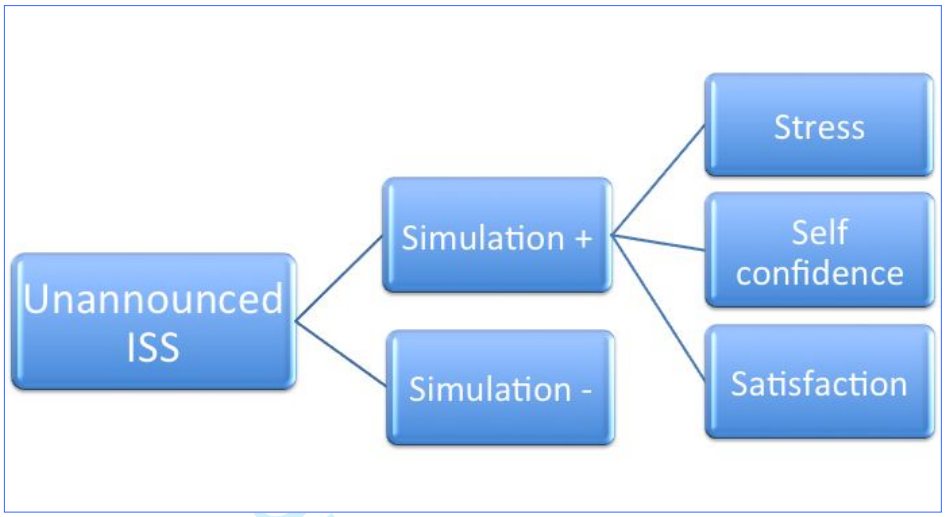


Figure 2. Phase 2



Online Supplementary material - Themes of semi-structured interviews

Métier :
Age :
Sexe :
Années d'expérience de travail :

Faire une courte en contexte de la recherche et du but de la rencontre [1]

1. **Les attentes des participants concernant la simulation**

- Avez-vous déjà fait l'expérience d'une simulation en lien avec les tâches liées à votre pratique

- Pourriez-vous me décrire les distinctions que vous feriez selon que ces simulations sont offertes directement sur votre lieu de pratique ou dans un autre espace de travail (avantages ou inconvénients perçus) ?

- Pourriez-vous me présenter vos préférences en matière de simulation, selon qu'elle est annoncée ou pas ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

- Sur le plan de l'organisation de votre travail, est-il plus pratique (du point de vue de votre efficacité) que ces simulations soient annoncées ou non ? et qu'elles soient intégrées à votre temps de travail ?

- Pourriez-vous me présenter vos préférences en matière de simulation, en distinguant les simulations réalistes (In Situ) vs les simulations hors In Situ ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

[1] Guide d'entretien; commenté par Steve Paquet pour Jennifer Truchot, **version du 3 mars 2020**

- Pourriez-vous me décrire les principaux facteurs positifs et négatifs de la simulation In Situ ? (Illustration par un cas exemple vécu)

- Pourriez-vous me parler des cas de simulation déjà expérimentés dans votre milieu de travail (réalisme, satisfaction, appréciation, plus-value de la démarche) ?

2. Pourriez-vous me dire quelques mots sur la nature des changements induits par la simulation sur les aspects organisationnels de votre milieu de pratique ?

3. **Appréhension et peur de participer**

- J'aimerais vous entendre sur vos appréhensions autour de ces pratiques de simulations.

- Parmi ces appréhensions, la peur de l'inconnu (par exemple ; nouveau cas clinique) est-elle un enjeu pour vous ?

- Parmi d'autres appréhensions possibles, la peur de se sentir évalué est-elle présente pour vous ?

- Serait-il possible de me décrire vos inquiétudes face aux jugements des autres en lien avec ces séances de simulation ? Pourriez-vous illustrer à l'aide de quelques exemples que vous auriez vécu ou rapportés par vos collègues ?

4. **Réflexion sur la simulation**

- J'aimerais avoir votre opinion quant à la sophistication des mannequins utilisés durant les exercices de simulation

- J'aimerais également recueillir quelques propos sur votre perception de votre environnement de travail qui peu, ou non, faciliter les séances de simulation

- Avez-vous l'impression que les apprentissages faits aux cours des simulations ont conduits au transfert des connaissances dans votre milieu de travail

5. **En guide de conclusion, que retirez-vous de vos différentes expériences de simulation, à partir des différentes dimensions que nous avons soulevées ensemble au cours de notre entretien (compétences cliniques ou non-techniques)**

6. **Auriez-vous d'autres points à discuter**

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine: a mixed method study protocol

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IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine - a mixed method study protocol

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ABSTRACT

Introduction:

In situ simulation (ISS) consists in performing a simulation in the everyday working environment with the usual team members. The feasibility of ISS in emergency medicine is an important research question, because ISS offers the possibility for repetitive, regular simulation training consistent with specific local needs. However, in situ simulation also raises the issue of safety, since it might negatively impact the care of other patients in the ED. Our hypothesis is that in situ simulation in an academic high-volume emergency department is feasible, safe, and associated with benefits for both staff and patients.

Methods:

A mixed method, including a qualitative method for the assessment of feasibility and acceptability and a quantitative method for the assessment of patients' safety and participants' psychosocial risks, will be used in this study.

Two distinct phases are planned in the emergency department of the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus). Phase 1: An ISS program will be implemented with selected emergency professionals to assess its acceptability and safety and prove the validity of our pedagogic concept. The number of cancelled sessions and the reasons for cancellation will be collected in order to establish feasibility criteria. Semi-structured interviews will evaluate the acceptability of the intervention. We will compare unannounced and announced ISS. Phase 2: The impact of the ISS program will be measured with validated questionnaires for the assessment of psychosocial risks, self-confidence and perceived stress among non-selected emergency professionals, with comparison between those exposed to ISS and those that were not.

Ethics and dissemination: The CHU de Québec-Université Laval Research ethics board has approved this protocol. Results will be presented to key professionals from our institution to improve patient safety. We also aim to publish our results in peer-reviewed journals and will submit abstracts to international conferences in order to disseminate our findings.

Keywords: Simulation, in situ, emergency medicine, acceptability, feasibility, safety, stress, satisfaction, burn out, professional wellbeing

Strengths and limitations of this study:

- This study is the first to simultaneously assess the acceptability, feasibility and safety of conducting ISS in a busy academic emergency department.
- The issue of patient safety during ISS is an important ethical consideration which is rarely included in simulation research.
- Even though ISS offers the possibility of improving patient safety through training, it can also jeopardize the quality of ongoing care by redirecting human resources from patients to the training process. The positive impact of ISS on patient outcomes was recently validated in a systematic review. However, these studies' analysis made no mention of patients' safety while ISS is being conducted.
- As it often is the case in simulation studies, the scope of our results might be restrained by methodological limitations such as the absence of randomization and the inability to blind participants to the outcome.

INTRODUCTION

Simulation is a teaching tool used for the acquisition of technical and non-technical skills.[1] Numerous studies have shown that simulation is associated with a significant beneficial effect for every health professional.[2, 3] This is also the case in emergency medicine (EM), which is a complex interprofessional specialty that requires a broad range of clinical knowledge as well as the mastery of multiple technical (i.e., intubation, chest tube insertion, lumbar puncture) and non-technical clinical skills (i.e., communication, task distribution, leadership and followership). Simulation enables new skill acquisition as well as continuing clinical education and training, which are necessary to manage both everyday situations and rare clinical cases. A wide variety of simulation aids exist, ranging from simple task manikins to virtual reality or hybrid simulation using live actors and manikins to increase realism.[4] The choice of the right tool must be based on a proper balance between learning objectives and the required level of realism. Realism, also called fidelity in simulation,[5] greatly impacts the quality of learning and especially the transfer of these skills to the real clinical world.[6] However, educators must carefully examine the stress generated by the simulation exercise. Stress can limit skill acquisition if the exercise is too complex for the participant's qualification and previous experience.[7, 8]

Simulation training can take place in a dedicated centre that is sometimes located off site, which consequently limits the training's wide implementation. Simulation centres necessitate human resources and structural expenditures, resulting in significant costs. The conditions they simulate are also quite different from those of the ED environment, thus decreasing the realism of the training.

It has also become increasingly difficult to get participants to engage in regular simulation training, especially when it is set to take place far from their usual workplace and outside usual working hours.[9-11] This is a problem for knowledge and skill retention given that effective learning seems to require repetition in training.[12] For example, the use of simulation is now recommended to teach and train basic and advanced life support (BLS and ALS).[13] A recent study found that the optimal training frequency for adequate retention of cardiopulmonary resuscitation (CPR) was once a month.[14] However, training all ED staff every month is impossible for most institutions.

In situ simulation (ISS), a type of simulation integrated into the targeted clinical environment, is a practical solution to these issues. The rationale for using it is based on the importance of environmental fidelity and its potential impact on learning.[15] Studies comparing simulation in a dedicated centre to in situ simulation are scarce. This could be due to the complex methodology required to implement them.[16] Nevertheless, a 2015 randomized study highlighted that participants' perception of realism was considerably higher in the in situ group.[16, 17]

ISS also offers the interesting possibility of identifying conditions—known as latent safety threats (LST)—that can lead to errors in the usual working environment.[18] LSTs are "system based threats to patient safety that can materialize at any time and are previously unrecognized by healthcare professionals and/or hospital administration."[19] One of the benefits of ISS is that since the simulations occur in a real-life environment, they enable the identification of LSTs such as equipment malfunctions or suboptimal team organization and responsibility awareness. This leads to a better understanding of potential errors and, therefore, to the possibility of reducing their incidence.[18] Numerous studies illustrate the positive impact, including improved patient outcomes, of ISS on the clinical practice of healthcare professionals from various specialties.[20-23] However, the complex environment of an ED can be challenging for those conducting ISS training. The difficult work conditions (overcrowding, task interruptions, understaffing) in emergency medicine can be a major practical limit to the implementation of ISS training.[24] The literature exploring different types of in situ simulation is still scant.[25] Different modalities have been compared through qualitative analysis and mostly using self-assessment tools.[25] For example, some authors compared unannounced ISS (outside of the scheduled work period) to announced ISS (during the scheduled work period) and found no difference in terms of preference or stress. These findings should be confirmed with objective and validated assessment tools combined with the exploration of more practical considerations, such as the safety of ISS itself. The ISS process can be used to enhance patient safety.[26] Simulation is an effective strategy for training many skills—including, as in this case, handover communication skills. Our work aims to confirm the innocuousness of ISS training. ISS is often used as a tool to improve the quality and safety of patient care, but it might also cause harm by redirecting resources and attention from patient care to the training process.

Therefore, our study will explore different modalities of exposure to in situ simulation in the emergency department: no ISS, announced ISS (outside the work shift) and unannounced ISS (unexpected simulation during the work shift).

Objectives

Primary objective

Phase 1: To assess and compare the feasibility and safety of two types of in situ simulation in the emergency department: announced and unannounced.

Phase 2: To assess whether ISS improves participants' psychosocial impact (stress reduction, satisfaction improvement) when compared to no exposure to ISS.

Secondary objectives

1) To compare the number of latent safety threats (LST) identified during unannounced ISS and announced ISS.(13)

METHODS AND ANALYSIS

Study design and setting

We will conduct a two-phase mixed-method study at the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus), a Canadian university-affiliated Level-1 trauma centre with an annual total of 67,000 visits. In this centre, the ED resuscitation/trauma team is activated by the triage nurse. All simulations will take place in the resuscitation/trauma area of the ED where real trauma patients are usually assessed upon their arrival.

Patient and public involvement

Patients or the public were not involved in the design of this study, nor will they be involved in its conduct or in the reporting and dissemination of our research.

Population

ED health professionals from the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus) will participate in the ISS training after informed verbal consent is obtained. Teams of seven participants will be involved in each of the sessions (three nurses, two emergency physicians, a respiratory therapist and a resident). The emergency physicians are either Royal College emergency specialists (FRCP) (five-year training) or emergency medicine-trained family physicians (three-year training) from the Canadian College of Family Physicians. This team size and composition exactly matches the trauma team that is activated when a real critical patient is admitted to the resuscitation/trauma area of our ED.

Phase 1 simulations will be announced, and participants will be selected volunteers.[27] During Phase 2, participation will be random, as the sessions will be unannounced.

Scenario design

Scenarios are inspired by real patients from a different ED in order to prevent participants from recognizing real cases, which may lead to increased stress and unsolicited cognitive load for some ED professionals.[28, 29] These scenarios will encompass common clinical presentations and will focus on two pathologies of interest for this ED: severe trauma (e.g., traumatic brain injury, penetrating thoracic trauma, massive transfusion protocol activation) and cardiac arrest. The simulation

team tested the scenarios beforehand during dedicated simulation training with a different population than the study participants. One of the key purposes for designing this study was to fulfil specific local teaching needs. Therefore, our tested training format will be useful to participants and could easily translate into improved patient care.

Simulations

For this study, we will use a Crash Kelly manikin from Laerdal (Laerdal Medical, Stavanger, Norway). Like other authors, we believe that the fidelity of the manikin itself is likely to be weakly correlated to the quality of learning,[30, 31] whereas the fidelity of the environment or of the scenario has a much greater probability of impacting the learning process.[6, 15, 32] We will use a thoracic prototype (created by one of the authors (CM)) to enhance realism and ensure flow immersion[33] for the scenarios requiring thoracic invasive intervention (insertion of a chest tube, thoracotomy). The different health professionals included in our study have all been exposed to manikins, prototypes and simulation training of this type within the emergency department's sim lab. They were familiarized with this material through interprofessional training for the residents' simulation program.

We will use real medications, with the exception of opioids and blood-derived products. If they are required for the simulation, we will reproduce blood products with saline bags coloured in red. For opioids, we will use saline with labels. We chose to use real medication to enhance realism and to better identify potential latent safety threats. Since training will take place in the trauma resuscitation area, the research team must limit the risks of mixing up real and fake medication.

In order to ensure patient safety and prevent disruptions to patient care in the ED during ISS, simulation experts have prepared a list of specific "go/no go" criteria. These criteria are based on the existing literature on ISS in clinical settings such as the ED,[34, 35] and we have adapted this list to some organizational specificities of our department. The "no go" criteria include heavy clinical load, understaffing, low bed availability on wards and equipment needs (e.g., unavailability of the fast flow fluid warmer). If a real trauma activation is expected or ongoing, the ISS will be cancelled and the simulation team will leave the trauma room in its original state. This system will not only enhance realism but also ensure safety.[35]

The ISS training sessions will be short—40 minutes in total (20 minutes of simulation, then 20 minutes of debriefing)[36]—and will follow the classic briefing-simulation-debriefing format.[37] Based on published reports[36, 38, 39] and our experience, keeping sessions and debriefings short greatly improves participant buy-in and reduces the impact on ED workflow. This approach was applied and successfully completed with a pre-defined objective of 30 minutes.[36, 38, 39]

Debriefing, an essential component of effective learning, will follow the plus delta model to optimize the educational impact for all participants.[40] This short format offers the possibility of repetitive simulation training and debriefing, whereas most traditional forms of sim training are rarely available to complete interprofessional teams.[11]

During each ISS, no matter the format, LST identification will be performed by an external observer with a specific LST grid identification tool.[18]

Procedure

Phase 1 (figure 1)

In the first phase of our study, we will assess the feasibility and safety of implementing announced or unannounced ISS during working shifts in a busy ED. A mixed method with a convergent design will be used.[41] Both qualitative and quantitative data will be collected within a similar timeframe. They will then be analyzed separately and merged.

Feasibility will be assessed via semi-structured individual interviews. Feasibility, according to Bowen *et al*., can be assessed through eight areas of focus: acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing.[42] Our study will assess the feasibility of each type of ISS with the following criteria: acceptability, implementation and practicality.

Acceptability and practicality, in particular, will be explored using semi-structured individual interviews, which will take place after the exposition to ISS and cover topics based on our preestablished thematic framework (see online supplementary material). The themes of the semi-structured interviews have been determined with the help of a qualitative research specialist and include previous professional experience and exposition to simulation, expectations, fear and thoughts regarding simulation training, and assessment of a preference for an ISS format (announced or

unannounced) (see online supplementary material). These interviews will take place at the end of Phase 1.

Another aspect of feasibility, implementation (i.e., the extent to which the simulation can be successfully conducted),[42] will be measured by compiling the number of cancelled sessions and the reasons for cancellation.

The number of identified LSTs during announced and unannounced ISS will also be collected. We hypothesize this number should be identical for both formats, and this is included in our feasibility analysis.

Safety is often an obstacle to ISS with working staff.[43] Indeed, even though this factor is rarely assessed and included in the methodology of research projects exploring ISS, it is reasonable to fear that during an ISS training session—especially a long one—ED staff may neglect the other patients under their care. This may lead to patients leaving without being seen, or unnoticed adverse events leading to increased morbidity or mortality. Therefore, quantitative parameters measuring the impact of these training sessions on patient care will be collected: 1) the ED median wait time six hours before and six hours after ISS (stretcher and ambulatory care separately) by triage category, and 2) the number of patients who left without being seen or against medical advice six hours after ISS. This information will be extracted from the institution's ED patient tracking software, and the data pertaining to the day of the unannounced ISS will be compared to that of the three days preceding the ISS, divided by working shifts (8 a.m. to 4 p.m., 4 p.m. to 12 a.m. and 12 a.m. to 8 a.m.). Dedicated research staff will be present in the ED during the simulations and for up to one hour afterwards in order to record the occurrence of reported patient-related adverse events (accident report) and the impact of the simulations on the working staff (understaffing and work overload). Official accident reports will be collected and reviewed as needed, and unreported adverse events will be categorized by research staff.

Phase 2 (figure 2)

Following Phase 1, we will implement unannounced ISS—simulations that will take place during a work shift without advance notice to participants. This second phase will focus on assessing the impacts of unannounced ISS on health professionals as regards psychosocial risks such as stress, self-confidence and professional wellbeing using validated satisfaction and stress scales.[44-46] The state anxiety questionnaire

will be used along with the measurement of perceived stress,[45] both validated for this type of methodology. The psychosocial risk assessment questionnaire and the assessment of self-confidence will reflect general professional wellbeing with validated assessment tools from the literature.[47, 48] In a recent study, simulation training provided a significant decrease in work stress among nurses in an intensive care unit.[44] To demonstrate this benefit, staff members exposed to either unannounced or announced ISS training (intervention group) will be compared to those that were not exposed to ISS (control group) using the same questionnaires. The questionnaires will be filled out by every healthcare professional working in the participating ED at the end of Phase 2 in order to compare the answers of the intervention group and the control group. Research assistants will collect the questionnaires with a tablet and ensure the completeness of our results.

Outcomes

Primary outcome:

Phase 1: Proportion of successful ISS and qualitative exploration of feasibility among the two groups: announced and unannounced

Phase 2: Psychosocial risks levels among the two groups: ISS and no ISS (intervention and control)

Secondary outcomes:

Phase 1:

- Quantitative patient safety parameters (wait times, adverse events, departures without being seen)
- Number of LSTs among the two groups: announced and unannounced

Phase 2:

- Self-confidence levels among the two groups: ISS and no ISS
- Stress levels among the two groups

Analyses

Number of sessions:

During Phase 1, a total of 16 sessions will be required (8 announced, 8 unannounced) with a total of 112 participants. This number is in line with previous literature in this field.[25]

We will conduct semi-directed interviews until we reach data saturation, with a view to including sufficient variety in the different socio-demographic characteristics of participants.

During Phase 2, a total of 10 unannounced ISS will be required to compare the group of participants exposed to ISS (n=70) to the professionals not exposed to ISS (n=70). Based on previous publication[44], this sample size will allow the detection of a 10% difference of the psychological demand score between groups (alpha: 0.05, power: 0.8).

Thematic content analyses

Audio-taped interviews will be transcribed and thematic content analysis will be performed by two independent evaluators using a deductive approach guided by the semi-structured interview's themes. The evaluators will follow Braun and Clarke's proposed six phases of thematic analyses.[49] We will use NVivo 12 Pro® software.

Quantitative analyses

The quantitative analyses will include comparisons between the different participating groups. Continuous data will be expressed as an average (standard deviation) when they are normally distributed and as a median [interquartile range Q1-Q3] otherwise. Continuous data will be analysed by paired t-tests, Wilcoxon signed-rank tests and multiple linear regression, if applicable. The categorical variables will be expressed in numbers (percentages). Categorical variables will be compared using the Chi-square test or the Fisher's exact test and logistic regression, if applicable. Bonferroni correction of multiple comparisons will be made. SAS® statistical software will be used for all statistical analysis.

Ethics and dissemination

The CHU de Québec-Université Laval Research ethics board approved our study. Potential participants to this study will receive an information form via email and in person before the announced ISS training. This information form will be distributed to every emergency professional and will include the research team's contact information should they have any question or should they refuse to participate in the study. Verbal consent will be obtained, and participants can withdraw at any time. The risks of participating in the study are no higher than when providing routine care to patients and/or during simulation training.

Limitations

Our study has some methodological limitations, most of which are inherent to simulation studies. ISS is new to the study site's ED. Therefore, to improve acceptance from the professionals, we have limited the number of announced and unannounced simulation to 8 each. Therefore, we will conduct eight announced and eight unannounced ISS, excluding the cancelled sessions. As each session will involve seven participants, the total numbers of participants should be a minimum of 112 emergency professionals. After Phase 1, we will adapt the number of ISS to the results obtained from our qualitative analysis. We accepted the selection bias created by the selection of volunteer participants during Phase 1. As the aim is to validate our concept, the recruitment of motivated volunteers from the ED staff seemed to be an acceptable limit to the generalization of our results. However, identifying and preparing selected participants is a widely accepted practice and is also recommended by change implementation experts.

For obvious reasons, randomizing participants would not have been ethically acceptable. It was also impossible to blind participants to the outcomes of the study, because the information form indicated they would have to fill out questionnaires and undergo semi-directed interviews. However, the analysis and group comparisons will respect allocation concealment. The statistician will be blinded to the nature of the intervention, and the research staff conducting the safety analysis and the qualitative analysis will be blinded to the "announced or unannounced" nature of the intervention.

It was difficult to find the optimal compromise between holding short, pragmatic and acceptable ISS training sessions (to limit the risks of negatively impacting ED

operations) and maintaining educational objectives to ensure effective learning. With these considerations in mind, we will choose "quieter" moments of the day to hold the simulations and will therefore be unable to reproduce the inherent chaos of the ED with perfect realism. Still, we feel this is an ethical imperative for a research team wishing to conduct ISS in a busy ED.

Dissemination strategy

This is the first scientific work to assess both feasibility and participant-centred outcomes. It is therefore an original, unexplored training situation, which may be associated with a practical clinical impact. ISS is a practical and safe teaching method that suits the specific constraints and needs pertaining to emergency medicine. In addition, one of the main limits to the wide implementation of simulation is its high cost. If ISS proves feasible in the ED, it could reduce the costs inherent to the structure (simulation centre) and associated human resources while increasing the safety of the process. Assessing the feasibility of a new intervention such as ISS and taking into account the opinions of the professionals involved will facilitate future implementation and uptake by targeted users. The impact of these training sessions on patient care could be measured through simple epidemiologic data collection. Improved care for severe trauma patients would also translate into lower public health costs. In addition, few studies exist on the importance of realism in simulation, but the importance of training in conditions close to real practice has already been shown.[32] For all these reasons, we are working in close partnership with important knowledge users from our institution toward a single, shared goal: to improve patient safety. Publications in peer-reviewed journals and international conferences presentations are also planned.

FIGURE LEGEND

Figure 1. Phase 1

Figure 2. Phase 2

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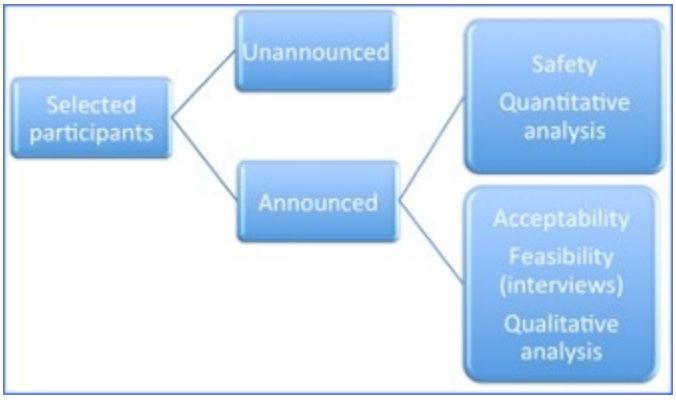

Figure 1. Phase 1

118x68mm (72 x 72 DPI)

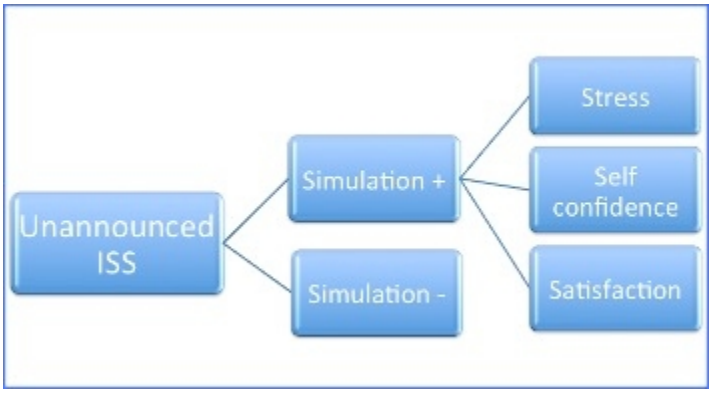

Figure 2. Phase 2

124x67mm (72 x 72 DPI)

Online Supplementary material - Themes of semi-structured interviews

Métier :
Age :
Sexe :
Années d'expérience de travail :

Faire une courte en contexte de la recherche et du but de la rencontre [1]

1. **Les attentes des participants concernant la simulation**

- Avez-vous déjà fait l'expérience d'une simulation en lien avec les tâches liées à votre pratique

- Pourriez-vous me décrire les distinctions que vous feriez selon que ces simulations sont offertes directement sur votre lieu de pratique ou dans un autre espace de travail (avantages ou inconvénients perçus) ?

- Pourriez-vous me présenter vos préférences en matière de simulation, selon qu'elle est annoncée ou pas ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

- Sur le plan de l'organisation de votre travail, est-il plus pratique (du point de vue de votre efficacité) que ces simulations soient annoncées ou non ? et qu'elles soient intégrées à votre temps de travail ?

- Pourriez-vous me présenter vos préférences en matière de simulation, en distinguant les simulations réalistes (In Situ) vs les simulations hors In Situ ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

[1] Guide d'entretien; commenté par Steve Paquet pour Jennifer Truchot, **version du 3 mars 2020**

- Pourriez-vous me décrire les principaux facteurs positifs et négatifs de la simulation In Situ ? (Illustration par un cas exemple vécu)

- Pourriez-vous me parler des cas de simulation déjà expérimentés dans votre milieu de travail (réalisme, satisfaction, appréciation, plus-value de la démarche) ?

2. Pourriez-vous me dire quelques mots sur la nature des changements induits par la simulation sur les aspects organisationnels de votre milieu de pratique ?

3. **Appréhension et peur de participer**

- J'aimerais vous entendre sur vos appréhensions autour de ces pratiques de simulations.

- Parmi ces appréhensions, la peur de l'inconnu (par exemple ; nouveau cas clinique) est-elle un enjeu pour vous ?

- Parmi d'autres appréhensions possibles, la peur de se sentir évalué est-elle présente pour vous ?

- Serait-il possible de me décrire vos inquiétudes face aux jugements des autres en lien avec ces séances de simulation ? Pourriez-vous illustrer à l'aide de quelques exemples que vous auriez vécu ou rapportés par vos collègues ?

4. **Réflexion sur la simulation**

- J'aimerais avoir votre opinion quant à la sophistication des mannequins utilisés durant les exercices de simulation

- J'aimerais également recueillir quelques propos sur votre perception de votre environnement de travail qui peu, ou non, faciliter les séances de simulation

- Avez-vous l'impression que les apprentissages faits aux cours des simulations ont conduits au transfert des connaissances dans votre milieu de travail

5. **En guide de conclusion, que retirez-vous de vos différentes expériences de simulation, à partir des différentes dimensions que nous avons soulevées ensemble au cours de notre entretien (compétences cliniques ou non-techniques)**

6. **Auriez-vous d'autres points à discuter**

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine: a mixed method study protocol

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Manuscript ID	bmjopen-2020-040360.R2
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Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Emergency medicine, Medical education and training
Keywords:	ACCIDENT & EMERGENCY MEDICINE, MEDICAL EDUCATION & TRAINING, TRAUMA MANAGEMENT

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IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine - a mixed method study protocol

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ABSTRACT

Introduction:

In situ simulation (ISS) consists in performing a simulation in the everyday working environment with the usual team members. The feasibility of ISS in emergency medicine is an important research question, because ISS offers the possibility for repetitive, regular simulation training consistent with specific local needs. However, in situ simulation also raises the issue of safety, since it might negatively impact the care of other patients in the ED. Our hypothesis is that in situ simulation in an academic high-volume emergency department is feasible, safe, and associated with benefits for both staff and patients.

Methods:

A mixed method, including a qualitative method for the assessment of feasibility and acceptability and a quantitative method for the assessment of patients' safety and participants' psychosocial risks, will be used in this study.

Two distinct phases are planned in the emergency department of the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus). Phase 1: An ISS program will be implemented with selected emergency professionals to assess its acceptability and safety and prove the validity of our pedagogic concept. The number of cancelled sessions and the reasons for cancellation will be collected in order to establish feasibility criteria. Semi-structured interviews will evaluate the acceptability of the intervention. We will compare unannounced and announced ISS. Phase 2: The impact of the ISS program will be measured with validated questionnaires for the assessment of psychosocial risks, self-confidence and perceived stress among non-selected emergency professionals, with comparison between those exposed to ISS and those that were not.

Ethics and dissemination: The CHU de Québec-Université Laval Research ethics board has approved this protocol (#2020-5000). Results will be presented to key professionals from our institution to improve patient safety. We also aim to publish our results in peer-reviewed journals and will submit abstracts to international conferences in order to disseminate our findings.

Keywords: Simulation, in situ, emergency medicine, acceptability, feasibility, safety, stress, satisfaction, burn out, professional wellbeing

Strengths and limitations of this study:

- This study is the first to simultaneously assess the acceptability, feasibility and safety of conducting ISS in a busy academic emergency department.
- The issue of patient safety during ISS is an important ethical consideration which is rarely included in simulation research.
- Even though ISS offers the possibility of improving patient safety through training, it can also jeopardize the quality of ongoing care by redirecting human resources from patients to the training process. The positive impact of ISS on patient outcomes was recently validated in a systematic review. However, these studies' analysis made no mention of patients' safety while ISS is being conducted.
- As it often is the case in simulation studies, the scope of our results might be restrained by methodological limitations such as the absence of randomization and the inability to blind participants to the outcome.

INTRODUCTION

Simulation is a teaching tool used for the acquisition of technical and non-technical skills.[1] Numerous studies have shown that simulation is associated with a significant beneficial effect for every health professional.[2, 3] This is also the case in emergency medicine (EM), which is a complex interprofessional specialty that requires a broad range of clinical knowledge as well as the mastery of multiple technical (i.e., intubation, chest tube insertion, lumbar puncture) and non-technical clinical skills (i.e., communication, task distribution, leadership and followership). Simulation enables new skill acquisition as well as continuing clinical education and training, which are necessary to manage both everyday situations and rare clinical cases. A wide variety of simulation aids exist, ranging from simple task manikins to virtual reality or hybrid simulation using live actors and manikins to increase realism.[4] The choice of the right tool must be based on a proper balance between learning objectives and the required level of realism. Realism, also called fidelity in simulation,[5] greatly impacts the quality of learning and especially the transfer of these skills to the real clinical world.[6] However, educators must carefully examine the stress generated by the simulation exercise. Stress can limit skill acquisition if the exercise is too complex for the participant's qualification and previous experience.[7, 8]

Simulation training can take place in a dedicated centre that is sometimes located off site, which consequently limits the training's wide implementation. Simulation centres necessitate human resources and structural expenditures, resulting in significant costs. The conditions they simulate are also quite different from those of the ED environment, thus decreasing the realism of the training.

It has also become increasingly difficult to get participants to engage in regular simulation training, especially when it is set to take place far from their usual workplace and outside usual working hours.[9-11] This is a problem for knowledge and skill retention given that effective learning seems to require repetition in training.[12] For example, the use of simulation is now recommended to teach and train basic and advanced life support (BLS and ALS).[13] A recent study found that the optimal training frequency for adequate retention of cardiopulmonary resuscitation (CPR) was once a month.[14] However, training all ED staff every month is impossible for most institutions.

In situ simulation (ISS), a type of simulation integrated into the targeted clinical environment, is a practical solution to these issues. The rationale for using it is based

on the importance of environmental fidelity and its potential impact on learning.[15] Studies comparing simulation in a dedicated centre to in situ simulation are scarce. This could be due to the complex methodology required to implement them.[16] Nevertheless, a 2015 randomized study highlighted that participants' perception of realism was considerably higher in the in situ group.[16, 17]

ISS also offers the interesting possibility of identifying conditions—known as latent safety threats (LST)—that can lead to errors in the usual working environment.[18] LSTs are "system based threats to patient safety that can materialize at any time and are previously unrecognized by healthcare professionals and/or hospital administration."[19] One of the benefits of ISS is that since the simulations occur in a real-life environment, they enable the identification of LSTs such as equipment malfunctions or suboptimal team organization and responsibility awareness. This leads to a better understanding of potential errors and, therefore, to the possibility of reducing their incidence.[18] Numerous studies illustrate the positive impact, including improved patient outcomes, of ISS on the clinical practice of healthcare professionals from various specialties.[20-23] However, the complex environment of an ED can be challenging for those conducting ISS training. The difficult work conditions (overcrowding, task interruptions, understaffing) in emergency medicine can be a major practical limit to the implementation of ISS training.[24] The literature exploring different types of in situ simulation is still scant.[25] Different modalities have been compared through qualitative analysis and mostly using self-assessment tools.[25] For example, some authors compared unannounced ISS (outside of the scheduled work period) to announced ISS (during the scheduled work period) and found no difference in terms of preference or stress. These findings should be confirmed with objective and validated assessment tools combined with the exploration of more practical considerations, such as the safety of ISS itself. The ISS process can be used to enhance patient safety.[26] Simulation is an effective strategy for training many skills—including, as in this case, handover communication skills. Our work aims to confirm the innocuousness of ISS training. ISS is often used as a tool to improve the quality and safety of patient care, but it might also cause harm by redirecting resources and attention from patient care to the training process.

Therefore, our study will explore different modalities of exposure to in situ simulation in the emergency department: no ISS (control group), announced ISS (outside the work shift) and unannounced ISS (unexpected simulation during the work shift).

Objectives

Primary objective

Phase 1: To assess and compare the feasibility of two types of in situ simulation in the emergency department: announced and unannounced.

Phase 2: To assess whether ISS improves participants' psychosocial impact (stress reduction, satisfaction and self confidence improvement) when compared to no exposure to ISS (control group).

Secondary objectives

1) To assess and compare the safety of two types of in situ simulation in the emergency department: announced and unannounced.

2) To compare the number of latent safety threats (LST) identified during unannounced ISS and announced ISS.(13)

METHODS AND ANALYSIS

Study design and setting

We will conduct a two-phase mixed-method study at the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus), a Canadian university-affiliated Level-1 trauma centre with an annual total of 67,000 visits. In this centre, the ED resuscitation/trauma team is activated by the triage nurse. All simulations will take place in the resuscitation/trauma area of the ED where real trauma patients are usually assessed upon their arrival.

Patient and public involvement

Patients or the public were not involved in the design of this study, nor will they be involved in its conduct or in the reporting and dissemination of our research.

Population

ED health professionals from the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus) will participate in the ISS training after informed verbal consent is obtained by research assistants. Teams of seven participants will be involved in each of the sessions (three nurses, two emergency physicians, a respiratory therapist and a resident). The emergency physicians are either Royal College emergency specialists (FRCP) (five-year training) or emergency medicine-trained family physicians (three-year training) from the Canadian College of Family Physicians. This team size and composition exactly matches the trauma team that is activated when a real critical patient is admitted to the resuscitation/trauma area of our ED.

Phase 1 simulations will be announced and unannounced. Participants will be selected volunteers.[27] During Phase 2, participation will be random, as the sessions will be only unannounced.

Scenario design

Scenarios are inspired by real patients from a different ED in order to prevent participants from recognizing real cases, which may lead to increased stress and unsolicited cognitive load for some ED professionals.[28, 29] These scenarios will encompass common clinical presentations and will focus on two pathologies of interest for this ED: severe trauma (e.g., traumatic brain injury, penetrating thoracic trauma, massive transfusion protocol activation) and cardiac arrest. The simulation team tested

the scenarios beforehand during dedicated simulation training with a different population than the study participants. One of the key purposes for designing this study was to fulfil specific local teaching needs. Therefore, our tested training format will be useful to participants and could easily translate into improved patient care.

Simulations

For this study, we will use a Crash Kelly manikin from Laerdal (Laerdal Medical, Stavanger, Norway). Like other authors, we believe that the fidelity of the manikin itself is likely to be weakly correlated to the quality of learning,[30, 31] whereas the fidelity of the environment or of the scenario has a much greater probability of impacting the learning process.[6, 15, 32] We will use a thoracic prototype (created by one of the authors (CM)) to enhance realism and ensure flow immersion[33] for the scenarios requiring thoracic invasive intervention (insertion of a chest tube, thoracotomy). The different health professionals included in our study have all been exposed to manikins, prototypes and simulation training of this type within the emergency department's sim lab. They were familiarized with this material through interprofessional training for the residents' simulation program.

We will use real medications, with the exception of opioids and blood-derived products. If they are required for the simulation, we will reproduce blood products with saline bags coloured in red. For opioids, we will use saline with labels. We chose to use real medication to enhance realism and to better identify potential latent safety threats. Since training will take place in the trauma resuscitation area, the research team must limit the risks of mixing up real and fake medication.

In order to ensure patient safety and prevent disruptions to patient care in the ED during ISS, simulation experts have prepared a list of specific "go/no go" criteria (see online supplementary material). These criteria are based on the existing literature on ISS in clinical settings such as the ED,[34, 35] and we have adapted this list to some organizational specificities of our department. The "no go" criteria include heavy clinical load, understaffing, low bed availability on wards and equipment needs (e.g., unavailability of the fast flow fluid warmer). If a real trauma activation is expected or ongoing, the ISS will be cancelled, and the simulation team will leave the trauma room in its original state. This system will not only enhance realism but also ensure safety.[35]

The ISS training sessions will be short—40 minutes in total (20 minutes of simulation, then 20 minutes of debriefing)[36]—and will follow the classic briefing-simulation-debriefing format.[37] Based on published reports[36, 38, 39] and our experience, keeping sessions and debriefings short greatly improves participant buy-in and reduces the impact on ED workflow. This approach was applied and successfully completed with a pre-defined objective of 30 minutes.[36, 38, 39]

Debriefing, an essential component of effective learning, will follow the plus delta model to optimize the educational impact for all participants.[40] This short format offers the possibility of repetitive simulation training and debriefing, whereas most traditional forms of sim training are rarely available to complete interprofessional teams.[11]

During each ISS, no matter the format, LST identification will be performed by an external observer with a specific LST grid identification tool.[18]

Procedure

Phase 1

In the first phase of our study (figure 1), we will assess the feasibility and safety of implementing announced or unannounced ISS during working shifts in a busy ED. A mixed method with a convergent design will be used.[41] Both qualitative and quantitative data will be collected within a similar timeframe and will then be analyzed separately and merged. Electronic study data will be kept in a password-protected file on the CHU de Québec-Université Laval's secure server. Paper data will be kept in a locked office within the CHU de Québec-Université Laval research center. In order to protect participant identity, all data will be denominalized and participants will be identified using a research number. The key code linking patient's name to the research number will be kept by the researcher in charge. All study data will be kept for 10 years and destroyed according to local modalities.

Feasibility will be assessed via semi-structured individual interviews. Feasibility, according to Bowen *et al*., can be assessed through eight areas of focus: acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing.[42] Our study will assess the feasibility of each type of ISS with the following criteria: acceptability, implementation and practicality.

Acceptability and practicality, in particular, will be explored using semi-structured individual interviews, which will take place after the exposition to ISS and cover topics based on our preestablished thematic framework (see online supplementary material). The themes of the semi-structured interviews have been determined with the help of a qualitative research specialist and include previous professional experience and exposition to simulation, expectations, fear and thoughts regarding simulation training, and assessment of a preference for an ISS format (announced or unannounced) (see online supplementary material). These interviews will take place at the end of Phase 1. Another aspect of feasibility, implementation (i.e., the extent to which the simulation can be successfully conducted),[42] will be measured by compiling the number of cancelled sessions with a descriptive analysis of the circumstances and the reasons for cancellation.

The number of identified LSTs during announced and unannounced ISS will also be collected. We hypothesize this number should be identical for both formats (announced or unannounced), and this is included in our feasibility analysis.

Safety is often an obstacle to ISS with working staff.[43] Indeed, even though this factor is rarely assessed and included in the methodology of research projects exploring ISS, it is reasonable to fear that during an ISS training session—especially a long one—ED staff may neglect the other patients under their care. This may lead to patients leaving without being seen, or unnoticed adverse events leading to increased morbidity or mortality. Therefore, quantitative parameters measuring the impact of these training sessions on patient care will be collected: 1) the ED median wait time six hours before and six hours after ISS (stretcher and ambulatory care separately) by triage category, and 2) the number of patients who left without being seen or against medical advice six hours after ISS. This information will be extracted from the institution's ED patient tracking software, and the data pertaining to the day of the unannounced ISS will be compared to that of the three days preceding the ISS, divided by working shifts (8 a.m. to 4 p.m., 4 p.m. to 12 a.m. and 12 a.m. to 8 a.m.). Dedicated research staff will be present in the ED during the simulations and for up to one hour afterwards in order to record the occurrence of reported patient-related adverse events (accident report) and the impact of the simulations on the working staff (understaffing and work overload). The research team will collect information regarding the impact of the training on the working staff using open-ended questions. Official accident reports will be collected

and reviewed as needed, and unreported adverse events will be categorized by research staff.

Phase 2

Following Phase 1, we will implement unannounced ISS—simulations that will take place during a work shift without advance notice to participants. This second phase (figure 2) will focus on assessing the impacts of unannounced ISS on health professionals as regards psychosocial risks such as stress, self-confidence and professional wellbeing using validated satisfaction and stress scales.[44-46] The state anxiety questionnaire will be used along with the measurement of perceived stress,[45] both validated for this type of methodology. The psychosocial risk assessment questionnaire and the assessment of self-confidence will reflect general professional wellbeing with validated assessment tools from the literature.[47, 48] In a recent study, simulation training provided a significant decrease in work stress among nurses in an intensive care unit.[44] To demonstrate this benefit, staff members exposed to either unannounced or announced ISS training (ISS group) will be compared to those that were not exposed to ISS (control group) using the same questionnaires. The questionnaires will be filled out by every healthcare professional working in the participating ED at the end of Phase 2 in order to compare the answers of the ISS group and the control group. Research assistants will collect the questionnaires with a tablet and ensure the completeness of our results.

Outcomes

Primary outcome:

Phase 1: Proportion of successful ISS and qualitative exploration of feasibility among the two groups: announced and unannounced

Phase 2: Psychosocial risks levels among the two groups: ISS and no ISS (control)

Secondary outcomes:

Phase 1:

- Quantitative patient safety parameters (wait times, adverse events, departures without being seen)
- Number of LSTs among the two groups: announced and unannounced

Phase 2:

- Self-confidence levels among the two groups: ISS and no ISS
- Stress levels among the two groups

Analyses

Number of sessions:

During Phase 1, a total of 16 sessions will be required (8 announced, 8 unannounced) with a total of 112 participants. This number is in line with previous literature in this field.[25]

We will conduct semi-directed interviews until we reach data saturation, with a view to including sufficient variety in the different socio-demographic characteristics of participants.

During Phase 2, a total of 10 unannounced ISS will be required to compare the group of participants exposed to ISS (n=70) to the professionals not exposed to ISS (n=70). Based on previous publication[44], this sample size will allow the detection of a 10% difference of the psychological demand score between groups (alpha: 0.05, power: 0.8).

Thematic content analyses

Audio-taped interviews will be transcribed, and thematic content analysis will be performed by two independent evaluators using a deductive approach guided by the semi-structured interview's themes. The evaluators will follow Braun and Clarke's proposed six phases of thematic analyses.[49] We will use NVivo 12 Pro® software. We have chosen to use the widely accepted and recognized criteria outlined by Lincoln and Guba to illustrate the quality of our study.[50, 51] To achieve credibility we will employ peer debriefing to provide an external validation of the research process. Participants will be given the chance to review the data collected by interviewers and the data's interpretations (member checking). This will offer the participants the opportunity to verify their statements and fill in any gaps from earlier interviews. We will provide thick descriptions to ensure transferability. To demonstrate dependability, we will ensure the research process is logical, traceable, and clearly documented. To achieve conformability, we will include markers such as the reasons for theoretical, methodological, and analytical choices throughout the entire study, so that others can

understand how and why decisions were made. A qualitative research expert and teacher from our university will be involved in each step of our research to provide guidance and ensure all of the above-mentioned quality control parameters.

Quantitative analyses

The quantitative analyses will include comparisons between the different participating groups. Continuous data will be expressed as an average (standard deviation) when they are normally distributed and as a median [interquartile range Q1-Q3] otherwise. Continuous data will be analysed by paired t-tests, Wilcoxon signed-rank tests and multiple linear regression, if applicable. The categorical variables will be expressed in numbers (percentages). Categorical variables will be compared using the Chi-square test or the Fisher's exact test and logistic regression, if applicable. Bonferroni correction of multiple comparisons will be made. SAS® statistical software will be used for all statistical analysis.

Ethics and dissemination

The CHU de Québec-Université Laval Research ethics board approved our study (#2020-5000). Potential participants to this study will receive an information form via email and in person before the announced ISS training. This information form will be distributed to every emergency professional and will include the research team's contact information should they have any question or should they refuse to participate in the study. Verbal consent will be obtained, and participants can withdraw at any time. The risks of participating in the study are no higher than when providing routine care to patients and/or during simulation training.

Limitations

Our study has some methodological limitations, most of which are inherent to simulation studies. ISS is new to the study site's ED. Therefore, to improve acceptance from the professionals, we have limited the number of announced and unannounced simulation to 8 each. Therefore, we will conduct eight announced and eight unannounced ISS, excluding the cancelled sessions. As each session will involve seven participants, the total numbers of participants should be a minimum of 112 emergency professionals. After Phase 1, we will adapt the number of ISS to the results obtained from our qualitative analysis. We accepted the selection bias created by the selection of volunteer participants during Phase 1. As the aim is to validate our concept, the recruitment of motivated volunteers from the ED staff seemed to be an acceptable limit to the generalization of our results. However, identifying and preparing selected participants is a widely accepted practice and is also recommended by change implementation experts.

For obvious reasons, randomizing participants would not have been ethically acceptable. It was also impossible to blind participants to the outcomes of the study, because the information form indicated they would have to fill out questionnaires and undergo semi-directed interviews. However, the analysis and group comparisons will respect allocation concealment. The statistician will be blinded to the nature of the intervention, and the research staff conducting the safety analysis and the qualitative analysis will be blinded to the "announced or unannounced" nature of the intervention. It was difficult to find the optimal compromise between holding short, pragmatic and acceptable ISS training sessions (to limit the risks of negatively impacting ED operations) and maintaining educational objectives to ensure effective learning. With

these considerations in mind, we will choose "quieter" moments of the day to hold the simulations and will therefore be unable to reproduce the inherent chaos of the ED with perfect realism. Still, we feel this is an ethical imperative for a research team wishing to conduct ISS in a busy ED.

Dissemination strategy

This is the first scientific work to assess both feasibility and participant-centred outcomes. It is therefore an original, unexplored training situation, which may be associated with a practical clinical impact. ISS is a practical and safe teaching method that suits the specific constraints and needs pertaining to emergency medicine. In addition, one of the main limits to the wide implementation of simulation is its high cost. If ISS proves feasible in the ED, it could reduce the costs inherent to the structure (simulation centre) and associated human resources while increasing the safety of the process. Assessing the feasibility of a new intervention such as ISS and taking into account the opinions of the professionals involved will facilitate future implementation and uptake by targeted users. The impact of these training sessions on patient care could be measured through simple epidemiologic data collection. Improved care for severe trauma patients would also translate into lower public health costs. In addition, few studies exist on the importance of realism in simulation, but the importance of training in conditions close to real practice has already been shown.[32] For all these reasons, we are working in close partnership with important knowledge users from our institution toward a single, shared goal: to improve patient safety. Publications in peer-reviewed journals and international conferences presentations are also planned.

FIGURE LEGEND

Figure 1. Phase 1

Figure 2. Phase 2

Contributorship statement: JT led the development of the protocol and drafted the manuscript. VB ERD & MÉ drafted the manuscript with the first author. CM, EB, JM, GM, GC, CG & GB critically revised and approved the final version of the manuscript.

Competing interest: None declared

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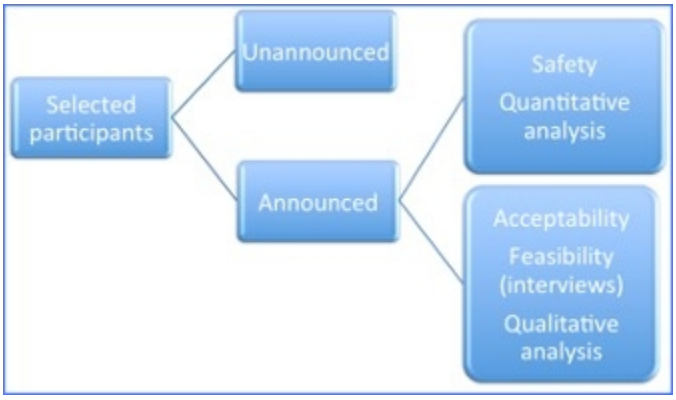

Figure 1. Phase 1

118x68mm (72 x 72 DPI)

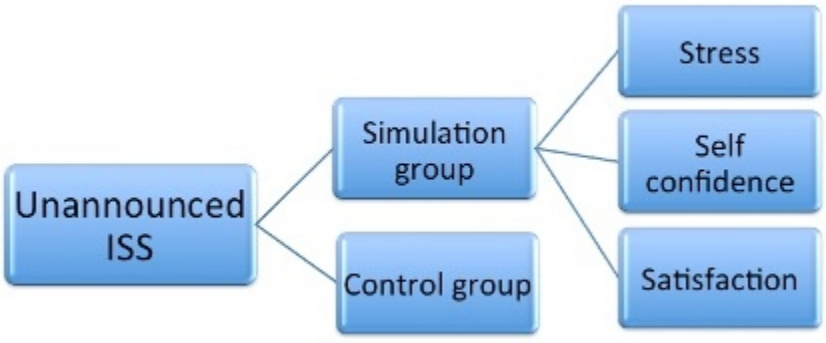

Figure 2. Phase 2

146x79mm (72 x 72 DPI)

Online Supplementary material - Themes of semi-structured interviews

Métier :
Age :
Sexe :
Années d'expérience de travail :

Faire une courte en contexte de la recherche et du but de la rencontre [1]

1. **Les attentes des participants concernant la simulation**

- Avez-vous déjà fait l'expérience d'une simulation en lien avec les tâches liées à votre pratique

- Pourriez-vous me décrire les distinctions que vous feriez selon que ces simulations sont offertes directement sur votre lieu de pratique ou dans un autre espace de travail (avantages ou inconvénients perçus) ?

- Pourriez-vous me présenter vos préférences en matière de simulation, selon qu'elle est annoncée ou pas ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

- Sur le plan de l'organisation de votre travail, est-il plus pratique (du point de vue de votre efficacité) que ces simulations soient annoncées ou non ? et qu'elles soient intégrées à votre temps de travail ?

- Pourriez-vous me présenter vos préférences en matière de simulation, en distinguant les simulations réalistes (In Situ) vs les simulations hors In Situ ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

[1] Guide d'entretien; commenté par Steve Paquet pour Jennifer Truchot, **version du 3 mars 2020**

- Pourriez-vous me décrire les principaux facteurs positifs et négatifs de la simulation In Situ ? (Illustration par un cas exemple vécu)

- Pourriez-vous me parler des cas de simulation déjà expérimentés dans votre milieu de travail (réalisme, satisfaction, appréciation, plus-value de la démarche) ?

2. Pourriez-vous me dire quelques mots sur la nature des changements induits par la simulation sur les aspects organisationnels de votre milieu de pratique ?

3. **Appréhension et peur de participer**

- J'aimerais vous entendre sur vos appréhensions autour de ces pratiques de simulations.

- Parmi ces appréhensions, la peur de l'inconnu (par exemple ; nouveau cas clinique) est-elle un enjeu pour vous ?

- Parmi d'autres appréhensions possibles, la peur de se sentir évalué est-elle présente pour vous ?

- Serait-il possible de me décrire vos inquiétudes face aux jugements des autres en lien avec ces séances de simulation ? Pourriez-vous illustrer à l'aide de quelques exemples que vous auriez vécu ou rapportés par vos collègues ?

4. **Réflexion sur la simulation**

- J'aimerais avoir votre opinion quant à la sophistication des mannequins utilisés durant les exercices de simulation

- J'aimerais également recueillir quelques propos sur votre perception de votre environnement de travail qui peu, ou non, faciliter les séances de simulation

- Avez-vous l'impression que les apprentissages faits aux cours des simulations ont conduits au transfert des connaissances dans votre milieu de travail

5. **En guide de conclusion, que retirez-vous de vos différentes expériences de simulation, à partir des différentes dimensions que nous avons soulevées ensemble au cours de notre entretien (compétences cliniques ou non-techniques)**

6. **Auriez-vous d'autres points à discuter**

Online Supplementary material - No go criteria

No go criteria to cancel the ISS training:

- Availability of the environment
- Medical Understaffing
- Non-medical Understaffing
- Overcrowding
- Heavy clinical load
- Low bed availability on wards
- Equipment needs (e.g., unavailability of the fast flow fluid warmer).
- If a real trauma activation is expected or ongoing
- Unanticipated Events/Threats to Psychological Safety

Online Supplementary material – Information sheet for participants

Feuillet d'information
Titre de l'étude : In Situ
Impact et acceptabilité de la simulation in situ aux urgences

Version approuvée par le CER du CHU de Québec-Université Laval le 23 janvier 2020
2020-5000

Chercheur principal local : Dr Marcel Emond

Préambule

Le Service de l'urgence de l'Hôpital de l'Enfant-Jésus du CHU de Québec-Université Laval mène une étude portant sur la simulation in situ comme nouvel outil pédagogique à l'urgence. Nous souhaitons recueillir les commentaires de médecins, infirmières, préposés, inhalothérapeutes et résidents dans le but d'améliorer le développement de ces formations.

Nous sollicitons votre participation à ce projet de recherche puisque vous travaillez dans le service de l'urgence de l'Hôpital de l'Enfant-Jésus du CHU de Québec-Université Laval. Cependant, avant d'accepter de participer à ce projet, veuillez prendre le temps de lire, de comprendre et de considérer attentivement les renseignements qui suivent. Nous vous invitons à poser toutes les questions que vous jugerez utiles au chercheur responsable de ce projet ou à un membre de son personnel de recherche et à leur demander de vous expliquer toute information qui n'est pas claire.

Nature et objectif de l'étude

Cette étude vise à améliorer la formation des professionnels de la santé de l'urgence et améliorer la qualité de vie au travail. L'objectif principal de ce projet consiste à évaluer la faisabilité et l'acceptabilité de mise en place de simulations in situ au Département d'urgence. Suite à ces simulations, nous tenterons d'évaluer si une diminution du stress et une augmentation de la confiance en soi peuvent être observées.

Déroulement du projet de recherche

Suite aux simulations, nous vous demanderons de participer à une entrevue enregistrée qui durera environ 45 minutes. Les entrevues auront lieu soit en personne, par téléphone ou via Skype/Zoom, avec un membre de l'équipe de recherche. Cette entrevue vous permettra de nous faire part de vos expériences lors de séances de simulation in situ à l'urgence. L'information que vous fournirez servira uniquement aux fins de cette étude. Certaines des questions seront de nature personnelle. Vous aurez l'option de ne pas répondre à toute question qui vous rendrait mal à l'aise.

Nous vous demanderons également de compléter à un questionnaire dont les réponses seront anonymisées. Ce questionnaire devrait prendre environ 15 minutes de votre temps.

Toutes les séances de simulation sont confidentielles et dans l'objectif unique d'améliorer les compétences techniques et non techniques. Il ne s'agit en aucun cas d'une évaluation.

Feuillet d'information
Titre de l'étude : In Situ
Impact et acceptabilité de la simulation in situ aux urgences

Participation volontaire et possibilité de retrait

Votre participation à ce projet de recherche est volontaire. Vous êtes donc libre de refuser d'y participer. Vous pouvez également vous retirer de ce projet à n'importe quel moment, sans avoir à donner de raisons, en informant l'équipe de recherche.

La décision de ne pas participer à ce projet de recherche ou de vous en retirer n'aura aucune conséquence sur votre emploi ou sur votre relation avec vos collègues.

Risques et inconvénients associés au projet de recherche

Vous pourriez être mal à l'aise lorsque vous discutez de vos expériences. Vous pouvez choisir de ne pas répondre aux questions ou de mettre fin à l'entrevue à tout moment si vous ressentez un inconfort. Outre le temps consacré à l'entrevue, aucun autre inconvénient associé à votre participation à cette étude n'est connu.

Avantages associés au projet de recherche

Il est possible que vous ne retiriez aucun avantage direct en prenant part à cette étude. Nous espérons que les renseignements obtenus lors de cette étude permettront d'aider les professionnels de la santé de l'urgence en démontrant que ce format nouveau de formation est faisable, acceptable et même bénéfique à la fois pour les professionnels de l'urgence mais aussi pour augmenter la sécurité des patients.

Confidentialité

Durant votre participation à ce projet, le chercheur responsable ainsi que son personnel recueilleront et consigneront dans un dossier de recherche les renseignements vous concernant. Seuls les renseignements nécessaires pour répondre aux objectifs scientifiques de ce projet seront recueillis. Tous les renseignements recueillis demeureront confidentiels dans les limites prévues par la loi. Afin de préserver votre identité et la confidentialité de vos renseignements, ce dernier sera identifié que par un numéro de code. La clé du code reliant votre nom à votre dossier de recherche sera conservée par l'équipe de recherche.

Le personnel de l'étude pourrait communiquer avec vous par courriel afin de prévoir un rendez-vous pour l'entrevue. La communication par courrier électronique n'est pas entièrement sécuritaire. Il est déconseillé de communiquer des renseignements personnels sensibles par courrier électronique.

Au cours des entrevues, les participants devront s'abstenir de nommer les personnes par leurs noms. Si des noms ou d'autres renseignements identifiants devaient être partagés pendant la discussion, ceux-ci ne seront pas inclus dans les transcriptions. Les enregistrements audio seront stockés en lieu sûr et seuls des membres de l'équipe de recherche pourront y avoir accès. Les enregistrements seront conservés jusqu'à ce qu'ils aient été transcrits (rédigés sous forme écrite), après quoi ils seront détruits. Les transcriptions seront conservées pendant une période de 10 ans.

Vos données anonymisées découlant de cette étude serviront uniquement à des fins de recherche. Les données de recherche pourront être publiées ou faire l'objet de discussions scientifiques, mais il ne sera pas possible de vous identifier.

À des fins de surveillance, de contrôle, de protection et de sécurité, votre dossier de recherche pourra être consulté par des représentants de l'établissement ou du comité d'éthique de la recherche. Ces personnes adhèrent à une politique de confidentialité.

Vous avez le droit d'être informé des résultats de cette étude une fois terminée. Si vous désirez être informé des résultats de cette étude, ou consulter votre dossier de recherche veuillez en informer l'équipe de recherche.

Feuillet d'information
Titre de l'étude : In Situ
Impact et acceptabilité de la simulation in situ aux urgences

Compensation

La participation aux formations sera rémunérée comme temps de travail et accrédité pour la formation continue.

Indemnisation en cas de préjudice et droits du participant à la recherche
En acceptant de participer à ce projet, vous ne renoncez à aucun de vos droits ni ne libérez le chercheur responsable de ce projet de leur responsabilité civile et professionnelle.

Identification des personnes-ressources
Si vous avez des questions ou éprouvez des problèmes en lien avec le projet de recherche, ou si vous souhaitez vous en retirer, vous pouvez communiquer avec le médecin responsable ou avec une personne de l'équipe de recherche au numéro suivant : (418) 649-0252, poste 66423.

Si vous avez des commentaires ou des questions à poser concernant vos droits en tant que participant à la recherche, ou si vous avez des plaintes ou des commentaires à formuler, vous pouvez communiquer avec la Commissaire locale aux plaintes et à la qualité des services du CHU de Québec – Université Laval au (418) 654-2211.

Surveillance des aspects éthiques du projet de recherche
Le comité d'éthique de la recherche du CHU de Québec-Université Laval a évalué la conformité du projet 2020-5000 aux principes qui gouvernent l'éthique de la recherche, et il en assurera le suivi.

En prenant part à cette entrevue, votre consentement à la participation à cette étude de recherche est implicite.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___N/A_____
	2b	All items from the World Health Organization Trial Registration Data Set	____ N/A _____
Protocol version	3	Date and version identifier	_____2_____
Funding	4	Sources and types of financial, material, and other support	_____1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1_____
	5b	Name and contact information for the trial sponsor	_____1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____1-2_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____ N/A _____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-7-8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figures

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_____14_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____N/A_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____ N/A _____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	____ N/A _____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____ N/A _____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____ N/A _____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___ N/A _____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_11-12-13-14-15_
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____ N/A ____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___11_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	____14-15_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	____N/A___
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	__ N/A _____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____N/A____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____ N/A ____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	____N/A_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____N/A____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___3_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____3____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____11_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____1-2_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	____ N/A ____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____ N/A _____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____17_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____ N/A ____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____ N/A ____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_ Online supplentary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	__ N/A _____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine: a mixed method study protocol

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Manuscript ID	bmjopen-2020-040360.R3
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Primary Subject Heading:	Emergency medicine
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IN SITU: Evaluation of the feasibility and impacts of in situ simulation in emergency medicine - a mixed method study protocol

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ABSTRACT

Introduction:

In situ simulation (ISS) consists in performing a simulation in the everyday working environment with the usual team members. The feasibility of ISS in emergency medicine is an important research question, because ISS offers the possibility for repetitive, regular simulation training consistent with specific local needs. However, in situ simulation also raises the issue of safety, since it might negatively impact the care of other patients in the Emergency Department (ED). Our hypothesis is that in situ simulation in an academic high-volume ED is feasible, safe, and associated with benefits for both staff and patients.

Methods:

A mixed method, including a qualitative method for the assessment of feasibility and acceptability and a quantitative method for the assessment of patients' safety and participants' psychosocial risks, will be used in this study.

Two distinct phases are planned in the ED of the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus) between March 2021 and October 2021. Phase 1: An ISS program will be implemented with selected ED professionals to assess its acceptability and safety and prove the validity of our educational concept. The number of cancelled sessions and the reasons for cancellation will be collected to establish feasibility criteria. Semi-structured interviews will evaluate the acceptability of the intervention. We will compare unannounced and announced ISS. Phase 2: The impact of the ISS program will be measured with validated questionnaires for the assessment of psychosocial risks, self-confidence and perceived stress among non-selected ED professionals, with comparison between those exposed to ISS and those that were not.

Ethics and dissemination:

The CHU de Québec-Université Laval Research ethics board has approved this protocol (#2020-5000). Results will be presented to key professionals from our institution to improve patient safety. We also aim to publish our results in peer-reviewed journals and will submit abstracts to international conferences to disseminate our findings.

Keywords: Simulation, in situ, emergency medicine, acceptability, feasibility, safety, stress, satisfaction, burn out, professional wellbeing

Strengths and limitations of this study:

- This study is the first to simultaneously assess the acceptability, feasibility and safety of conducting ISS in a busy academic emergency department.
- The issue of patient safety during ISS is an important ethical consideration, which is rarely included in the design of simulation research.
- Even though ISS offers the possibility of improving patient safety through training, it can also jeopardize the quality of ongoing care by redirecting human resources from patients to the training process.
- The positive impact of ISS on patient outcomes was highlighted in a systematic review, however, without mention of patients' safety.
- As it often is the case in simulation studies, the scope of our results might be restrained by methodological limitations such as the absence of randomization and the inability to blind participants to the outcome.

INTRODUCTION

Simulation is a teaching tool used for the acquisition of technical and non-technical skills.[1] Numerous studies have shown that simulation is associated with a significant beneficial effect for every health professional.[2, 3] This is also the case in emergency medicine (EM), which is a complex interprofessional specialty that requires a broad range of clinical knowledge as well as the mastery of multiple technical (i.e., intubation, chest tube insertion, lumbar puncture) and non-technical clinical skills (i.e., communication, task distribution, leadership and followership). Simulation enables new skill acquisition as well as continuing clinical education and training, which are necessary to manage both everyday situations and rare clinical cases. A wide variety of simulation aids exist, ranging from simple task manikins to virtual reality or hybrid simulation using live actors and manikins to increase realism.[4] The choice of the right tool must be based on a proper balance between learning objectives and the required level of realism. Realism, also called fidelity in simulation,[5] greatly impacts the quality of learning and especially the transfer of these skills to the real clinical world.[6] However, educators must carefully examine the stress generated by the simulation exercise. Stress can limit skill acquisition if the exercise is too complex for the participant's qualification and previous experience.[7, 8]

Simulation training can take place in a dedicated centre that is sometimes located off site, which consequently limits the training's wide implementation. Simulation centres necessitate human resources and structural expenditures, resulting in significant costs. The conditions they simulate are also quite different from those of the ED environment, thus decreasing the realism of the training.

It has also become increasingly difficult to get participants to engage in regular simulation training, especially when it is set to take place far from their usual workplace and outside usual working hours.[9-11] This is a problem for knowledge and skill retention given that effective learning seems to require repetition in training.[12] For example, the use of simulation is now recommended to teach and train basic and advanced life support (BLS and ALS).[13] A recent study found that the optimal training frequency for adequate retention of cardiopulmonary resuscitation (CPR) was once a month.[14] However, training all ED staff every month is impossible for most institutions.

In situ simulation (ISS), a type of simulation integrated into the targeted clinical environment, is a practical solution to these issues. The rationale for using it is based on the importance of environmental fidelity and its potential impact on learning.[15] Studies comparing simulation in a dedicated centre to in situ simulation are scarce. This could be due to the complex methodology required to implement them.[16] Nevertheless, a 2015 randomized study highlighted that participants' perception of realism was considerably higher in the in situ group.[16, 17]

ISS also offers the interesting possibility of identifying conditions—known as latent safety threats (LST)—that can lead to errors in the usual working environment.[18] LSTs are "system based threats to patient safety that can materialize at any time and are previously unrecognized by healthcare professionals and/or hospital administration."[19] One of the benefits of ISS is that since the simulations occur in a real-life environment, they enable the identification of LSTs such as equipment malfunctions or suboptimal team organization and responsibility awareness. This leads to a better understanding of potential errors and, therefore, to the possibility of reducing their incidence.[18] Numerous studies illustrate the positive impact, including improved patient outcomes, of ISS on the clinical practice of healthcare professionals from various specialties.[20-23] However, the complex environment of an ED can be challenging for those conducting ISS training. The difficult work conditions (overcrowding, task interruptions, understaffing) in emergency medicine can be a major practical limit to the implementation of ISS training.[24] The literature exploring different types of in situ simulation is still scant.[25] Different modalities have been compared through qualitative analysis and mostly using self-assessment tools.[25] For example, some authors compared unannounced ISS (outside of the scheduled work period) to announced ISS (during the scheduled work period) and found no difference in terms of preference or stress. These findings should be confirmed with objective and validated assessment tools combined with the exploration of more practical considerations, such as the safety of ISS itself. The ISS process can be used to enhance patient safety.[26] Simulation is an effective strategy for training many skills—including, as in this case, handover communication skills. Our work aims to confirm the innocuousness of ISS training. ISS is often used as a tool to improve the quality and safety of patient care, but it might also cause harm by redirecting resources and attention from patient care to the training process.

Therefore, our study will explore different modalities of exposure to in situ simulation in the emergency department: no ISS (control group), announced ISS (outside the work shift) and unannounced ISS (unexpected simulation during the work shift).

Objectives

Primary objective

Phase 1: To assess and compare the feasibility of two types of in situ simulation in the emergency department: announced and unannounced.

Phase 2: To assess whether ISS improves participants' psychosocial impact (stress reduction, satisfaction and self confidence improvement) when compared to no exposure to ISS (control group).

Secondary objectives

1) To assess and compare the safety of two types of in situ simulation in the emergency department: announced and unannounced.

2) To compare the number of latent safety threats (LST) identified during unannounced ISS and announced ISS.(13)

METHODS AND ANALYSIS

Study design and setting

We will conduct a two-phase mixed-method study at the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus), a Canadian university-affiliated Level-1 trauma centre with an annual total of 67,000 visits. In this centre, the ED resuscitation/trauma team is activated by the triage nurse. All simulations will take place between March 2021 and October 2021 in the resuscitation/trauma area of the ED where real trauma patients are usually assessed upon their arrival.

Patient and public involvement

Patients or the public were not involved in the design of this study, nor will they be involved in its conduct or in the reporting and dissemination of our research.

Population

ED health professionals from the CHU de Québec-Université Laval (Hôpital de l'Enfant-Jésus) will participate in the ISS training after informed verbal consent is obtained by research assistants. Teams of seven participants will be involved in each of the sessions (three nurses, two emergency physicians, a respiratory therapist and a resident). The emergency physicians are either Royal College emergency specialists (FRCP) (five-year training) or emergency medicine-trained family physicians (three-year training) from the Canadian College of Family Physicians. This team size and composition exactly matches the trauma team that is activated when a real critical patient is admitted to the resuscitation/trauma area of our ED.

Phase 1 simulations will be announced and unannounced. Participants will be selected volunteers.[27] During Phase 2, participation will be random, as the sessions will be only unannounced.

Scenario design

Scenarios are inspired by real patients from a different ED in order to prevent participants from recognizing real cases, which may lead to increased stress and unsolicited cognitive load for some ED professionals.[28, 29] These scenarios will encompass common clinical presentations and will focus on two pathologies of interest for this ED: severe trauma (e.g., traumatic brain injury, penetrating thoracic trauma, massive transfusion protocol activation) and cardiac arrest. The simulation

team tested the scenarios beforehand during dedicated simulation training with a different population than the study participants. One of the key purposes for designing this study was to fulfil specific local teaching needs. Therefore, our tested training format will be useful to participants and could easily translate into improved patient care.

Simulations

For this study, we will use a Crash Kelly manikin from Laerdal (Laerdal Medical, Stavanger, Norway). Like other authors, we believe that the fidelity of the manikin itself is likely to be weakly correlated to the quality of learning,[30, 31] whereas the fidelity of the environment or of the scenario has a much greater probability of impacting the learning process.[6, 15, 32] We will use a thoracic prototype (created by one of the authors (CM)) to enhance realism and ensure flow immersion[33] for the scenarios requiring thoracic invasive intervention (insertion of a chest tube, thoracotomy). The different health professionals included in our study have all been exposed to manikins, prototypes and simulation training of this type within the emergency department's sim lab. They were familiarized with this material through interprofessional training for the residents' simulation program.

We will use real medications, with the exception of opioids and blood-derived products. If they are required for the simulation, we will reproduce blood products with saline bags coloured in red. For opioids, we will use saline with labels. We chose to use real medication to enhance realism and to better identify potential latent safety threats. Since training will take place in the trauma resuscitation area, the research team must limit the risks of mixing up real and fake medication.

In order to ensure patient safety and prevent disruptions to patient care in the ED during ISS, simulation experts have prepared a list of specific "go/no go" criteria (see online supplementary material). These criteria are based on the existing literature on ISS in clinical settings such as the ED,[34, 35] and we have adapted this list to some organizational specificities of our department. The "no go" criteria include heavy clinical load, understaffing, low bed availability on wards and equipment needs (e.g., unavailability of the fast flow fluid warmer). If a real trauma activation is expected or ongoing, the ISS will be cancelled, and the simulation team will leave the trauma room in its original state. This system will not only enhance realism but also ensure safety.[35]

The ISS training sessions will be short—40 minutes in total (20 minutes of simulation, then 20 minutes of debriefing)[36]—and will follow the classic briefing-simulation-debriefing format.[37] Based on published reports[36, 38, 39] and our experience, keeping sessions and debriefings short greatly improves participant buy-in and reduces the impact on ED workflow. This approach was applied and successfully completed with a pre-defined objective of 30 minutes.[36, 38, 39]

Debriefing, an essential component of effective learning, will follow the plus delta model to optimize the educational impact for all participants.[40] This short format offers the possibility of repetitive simulation training and debriefing, whereas most traditional forms of sim training are rarely available to complete interprofessional teams.[11]

During each ISS, no matter the format, LST identification will be performed by an external observer with a specific LST grid identification tool.[18]

Procedure

Phase 1

In the first phase of our study (figure 1), we will assess the feasibility and safety of implementing announced or unannounced ISS during working shifts in a busy ED. A mixed method with a convergent design will be used.[41] Both qualitative and quantitative data will be collected within a similar timeframe and will then be analyzed separately and merged. Electronic study data will be kept in a password-protected file on the CHU de Québec-Université Laval's secure server. Paper data will be kept in a locked office within the CHU de Québec-Université Laval research center. In order to protect participant identity, all data will be denominalized and participants will be identified using a research number. The key code linking patient's name to the research number will be kept by the researcher in charge. All study data will be kept for 10 years and destroyed according to local modalities.

Feasibility will be assessed via semi-structured individual interviews. Feasibility, according to Bowen *et al*., can be assessed through eight areas of focus: acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing.[42] Our study will assess the feasibility of each type of ISS with the following criteria: acceptability, implementation and practicality.

Acceptability and practicality, in particular, will be explored using semi-structured individual interviews, which will take place after the exposition to ISS and cover topics based on our preestablished thematic framework (see online supplementary material). The themes of the semi-structured interviews have been determined with the help of a qualitative research specialist and include previous professional experience and exposition to simulation, expectations, fear and thoughts regarding simulation training, and assessment of a preference for an ISS format (announced or unannounced) (see online supplementary material). These interviews will take place at the end of Phase 1.

Another aspect of feasibility, implementation (i.e., the extent to which the simulation can be successfully conducted),[42] will be measured by compiling the number of cancelled sessions with a descriptive analysis of the circumstances and the reasons for cancellation.

The number of identified LSTs during announced and unannounced ISS will also be collected. We hypothesize this number should be identical for both formats (announced or unannounced), and this is included in our feasibility analysis.

Safety is often an obstacle to ISS with working staff.[43] Indeed, even though this factor is rarely assessed and included in the methodology of research projects exploring ISS, it is reasonable to fear that during an ISS training session—especially a long one—ED staff may neglect the other patients under their care. This may lead to patients leaving without being seen, or unnoticed adverse events leading to increased morbidity or mortality. Therefore, quantitative parameters measuring the impact of these training sessions on patient care will be collected: 1) the ED median wait time six hours before and six hours after ISS (stretcher and ambulatory care separately) by triage category, and 2) the number of patients who left without being seen or against medical advice six hours after ISS. This information will be extracted from the institution's ED patient tracking software, and the data pertaining to the day of the unannounced ISS will be compared to that of the three days preceding the ISS, divided by working shifts (8 a.m. to 4 p.m., 4 p.m. to 12 a.m. and 12 a.m. to 8 a.m.). Dedicated research staff will be present in the ED during the simulations and for up to one hour afterwards in order to record the occurrence of reported patient-related adverse events (accident report) and the impact of the simulations on the working staff (understaffing and work overload). The research team will collect information regarding the impact of the training on the working staff using open-ended questions.

Official accident reports will be collected and reviewed as needed, and unreported adverse events will be categorized by research staff.

Phase 2

Following Phase 1, we will implement unannounced ISS—simulations that will take place during a work shift without advance notice to participants. This second phase (figure 2) will focus on assessing the impacts of unannounced ISS on health professionals as regards psychosocial risks such as stress, self-confidence and professional wellbeing using validated satisfaction and stress scales.[44-46] The state anxiety questionnaire will be used along with the measurement of perceived stress,[45] both validated for this type of methodology. The psychosocial risk assessment questionnaire and the assessment of self-confidence will reflect general professional wellbeing with validated assessment tools from the literature.[47, 48] In a recent study, simulation training provided a significant decrease in work stress among nurses in an intensive care unit.[44] To demonstrate this benefit, staff members exposed to either unannounced or announced ISS training (ISS group) will be compared to those that were not exposed to ISS (control group) using the same questionnaires. The questionnaires will be filled out by every healthcare professional working in the participating ED at the end of Phase 2 in order to compare the answers of the ISS group and the control group. Research assistants will collect the questionnaires with a tablet and ensure the completeness of our results.

Outcomes

Primary outcome:

Phase 1: Proportion of successful ISS and qualitative exploration of feasibility among the two groups: announced and unannounced

Phase 2: Psychosocial risks levels among the two groups: ISS and no ISS (control)

Secondary outcomes:

Phase 1:

- Quantitative patient safety parameters (wait times, adverse events, departures without being seen)
- Number of LSTs among the two groups: announced and unannounced

Phase 2:

- Self-confidence levels among the two groups: ISS and no ISS
- Stress levels among the two groups

Analyses

Number of sessions:

During Phase 1, a total of 16 sessions will be required (8 announced, 8 unannounced) with a total of 112 participants. This number is in line with previous literature in this field.[25]

We will conduct semi-directed interviews until we reach data saturation, with a view to including sufficient variety in the different socio-demographic characteristics of participants.

During Phase 2, a total of 10 unannounced ISS will be required to compare the group of participants exposed to ISS (n=70) to the professionals not exposed to ISS (n=70). Based on previous publication[44], this sample size will allow the detection of a 10% difference of the psychological demand score between groups (alpha: 0.05, power: 0.8).

Thematic content analyses

Audio-taped interviews will be transcribed, and thematic content analysis will be performed by two independent evaluators using a deductive approach guided by the semi-structured interview's themes. The evaluators will follow Braun and Clarke's proposed six phases of thematic analyses.[49] We will use NVivo 12 Pro® software. We have chosen to use the widely accepted and recognized criteria outlined by Lincoln and Guba to illustrate the quality of our study.[50, 51] To achieve credibility we will employ peer debriefing to provide an external validation of the research process. Participants will be given the chance to review the data collected by interviewers and the data's interpretations (member checking). This will offer the participants the opportunity to verify their statements and fill in any gaps from earlier interviews. We will provide thick descriptions to ensure transferability. To demonstrate dependability, we will ensure the research process is logical, traceable, and clearly documented. To achieve conformability, we will include markers such as

the reasons for theoretical, methodological, and analytical choices throughout the entire study, so that others can understand how and why decisions were made. A qualitative research expert and teacher from our university will be involved in each step of our research to provide guidance and ensure all of the above-mentioned quality control parameters.

Quantitative analyses

The quantitative analyses will include comparisons between the different participating groups. Continuous data will be expressed as an average (standard deviation) when they are normally distributed and as a median [interquartile range Q1-Q3] otherwise. Continuous data will be analysed by paired t-tests, Wilcoxon signed-rank tests and multiple linear regression, if applicable. The categorical variables will be expressed in numbers (percentages). Categorical variables will be compared using the Chi-square test or the Fisher's exact test and logistic regression, if applicable. Bonferroni correction of multiple comparisons will be made. SAS® statistical software will be used for all statistical analysis.

Ethics and dissemination

The CHU de Québec-Université Laval Research ethics board approved our study (#2020-5000). Potential participants to this study will receive an information form via email and in person before the announced ISS training. This information form will be distributed to every emergency professional and will include the research team's contact information should they have any question or should they refuse to participate in the study. Verbal consent will be obtained, and participants can withdraw at any time. The risks of participating in the study are no higher than when providing routine care to patients and/or during simulation training.

Limitations

Our study has some methodological limitations, most of which are inherent to simulation studies. ISS is new to the study site's ED. Therefore, to improve acceptance from the professionals, we have limited the number of announced and unannounced simulation to 8 each. Therefore, we will conduct eight announced and eight unannounced ISS, excluding the cancelled sessions. As each session will involve seven participants, the total numbers of participants should be a minimum of 112 emergency professionals. After Phase 1, we will adapt the number of ISS to the results obtained from our qualitative analysis. We accepted the selection bias created by the selection of volunteer participants during Phase 1. As the aim is to validate our concept, the recruitment of motivated volunteers from the ED staff seemed to be an acceptable limit to the generalization of our results. However, identifying and preparing selected participants is a widely accepted practice and is also recommended by change implementation experts.

For obvious reasons, randomizing participants would not have been ethically acceptable. It was also impossible to blind participants to the outcomes of the study, because the information form indicated they would have to fill out questionnaires and undergo semi-directed interviews. However, the analysis and group comparisons will respect allocation concealment. The statistician will be blinded to the nature of the intervention, and the research staff conducting the safety analysis and the qualitative analysis will be blinded to the "announced or unannounced" nature of the intervention.

It was difficult to find the optimal compromise between holding short, pragmatic and acceptable ISS training sessions (to limit the risks of negatively impacting ED

operations) and maintaining educational objectives to ensure effective learning. With these considerations in mind, we will choose "quieter" moments of the day to hold the simulations and will therefore be unable to reproduce the inherent chaos of the ED with perfect realism. Still, we feel this is an ethical imperative for a research team wishing to conduct ISS in a busy ED.

Dissemination strategy

This is the first scientific work to assess both feasibility and participant-centred outcomes. It is therefore an original, unexplored training situation, which may be associated with a practical clinical impact. ISS is a practical and safe teaching method that suits the specific constraints and needs pertaining to emergency medicine. In addition, one of the main limits to the wide implementation of simulation is its high cost. If ISS proves feasible in the ED, it could reduce the costs inherent to the structure (simulation centre) and associated human resources while increasing the safety of the process. Assessing the feasibility of a new intervention such as ISS and taking into account the opinions of the professionals involved will facilitate future implementation and uptake by targeted users. The impact of these training sessions on patient care could be measured through simple epidemiologic data collection. Improved care for severe trauma patients would also translate into lower public health costs. In addition, few studies exist on the importance of realism in simulation, but the importance of training in conditions close to real practice has already been shown.[32] For all these reasons, we are working in close partnership with important knowledge users from our institution toward a single, shared goal: to improve patient safety. Publications in peer-reviewed journals and international conferences presentations are also planned.

FIGURE LEGEND

Figure 1. Phase 1

Figure 2. Phase 2

Contributorship statement: JT led the development of the protocol and drafted the manuscript. VB ERD & MÉ drafted the manuscript with the first author. CM, EB, JM, GM, GC, CG & GB critically revised and approved the final version of the manuscript.

Competing interest: None declared

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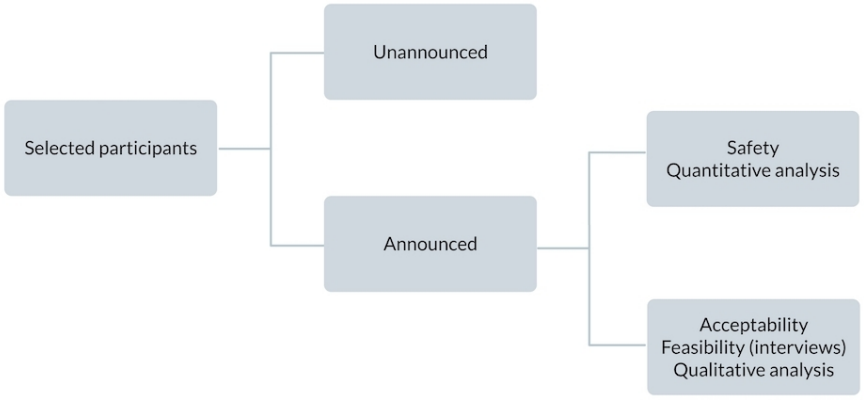

Figure 1. Phase 1

90x90mm (300 x 300 DPI)

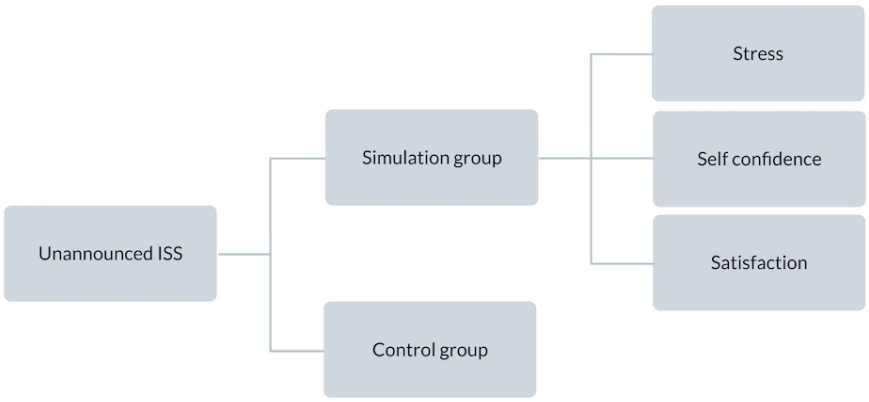

Figure 2. Phase 2

90x90mm (300 x 300 DPI)

Online Supplementary material - Themes of semi-structured interviews

Métier :
Age :
Sexe :
Années d'expérience de travail :

Faire une courte en contexte de la recherche et du but de la rencontre [1]

1. **Les attentes des participants concernant la simulation**

- Avez-vous déjà fait l'expérience d'une simulation en lien avec les tâches liées à votre pratique

- Pourriez-vous me décrire les distinctions que vous feriez selon que ces simulations sont offertes directement sur votre lieu de pratique ou dans un autre espace de travail (avantages ou inconvénients perçus) ?

- Pourriez-vous me présenter vos préférences en matière de simulation, selon qu'elle est annoncée ou pas ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

- Sur le plan de l'organisation de votre travail, est-il plus pratique (du point de vue de votre efficacité) que ces simulations soient annoncées ou non ? et qu'elles soient intégrées à votre temps de travail ?

- Pourriez-vous me présenter vos préférences en matière de simulation, en distinguant les simulations réalistes (In Situ) vs les simulations hors In Situ ?

    - Du point de vue du degré d'engagement
    - De l'immersion
    - Durée du débriefing
    - Apprentissage acquis (individuel ou par équipe)

[1] Guide d'entretien; commenté par Steve Paquet pour Jennifer Truchot, **version du 3 mars 2020**

- Pourriez-vous me décrire les principaux facteurs positifs et négatifs de la simulation In Situ ? (Illustration par un cas exemple vécu)

- Pourriez-vous me parler des cas de simulation déjà expérimentés dans votre milieu de travail (réalisme, satisfaction, appréciation, plus-value de la démarche) ?

2. Pourriez-vous me dire quelques mots sur la nature des changements induits par la simulation sur les aspects organisationnels de votre milieu de pratique ?

3. **Appréhension et peur de participer**

- J'aimerais vous entendre sur vos appréhensions autour de ces pratiques de simulations.

- Parmi ces appréhensions, la peur de l'inconnu (par exemple ; nouveau cas clinique) est-elle un enjeu pour vous ?

- Parmi d'autres appréhensions possibles, la peur de se sentir évalué est-elle présente pour vous ?

- Serait-il possible de me décrire vos inquiétudes face aux jugements des autres en lien avec ces séances de simulation ? Pourriez-vous illustrer à l'aide de quelques exemples que vous auriez vécu ou rapportés par vos collègues ?

4. **Réflexion sur la simulation**

- J'aimerais avoir votre opinion quant à la sophistication des mannequins utilisés durant les exercices de simulation

- J'aimerais également recueillir quelques propos sur votre perception de votre environnement de travail qui peu, ou non, faciliter les séances de simulation

- Avez-vous l'impression que les apprentissages faits aux cours des simulations ont conduits au transfert des connaissances dans votre milieu de travail

5. **En guide de conclusion, que retirez-vous de vos différentes expériences de simulation, à partir des différentes dimensions que nous avons soulevées ensemble au cours de notre entretien (compétences cliniques ou non-techniques)**

6. **Auriez-vous d'autres points à discuter**

Online Supplementary material - No go criteria

No go criteria to cancel the ISS training:

- **Availability of the environment:** The ED's trauma/resuscitation area has the possibility of simultaneously managing three patients with acute conditions such as trauma, respiratory distress, cardiac arrest, or any other acute distress. If two real patients already occupy these beds when an ISS is supposed to take place, it will be cancelled.
- **Medical Understaffing:** During the unannounced ISS sessions, the ED staff involved in the training will be implicated at the same time in real patients care. The usual number of medical staff for day or evening shifts during the week is four emergency physicians and up to three medical residents. Unannounced ISS will be cancelled if 50% of emergency physicians on shift are attending real critical care patients or absent the day of the training.
- **Nursing Understaffing**: When ISS is unannounced and therefore requires the participation of staff already implicated in patients' care, we will cancel ISS if the ED is more than one nurse short.
- **Overcrowding / Low bed availability on wards:** These criteria were defined by Quebec's Ministry of Health (Ministère de la Santé et des Services sociaux). We will cancel ISS when level 2 is reached. The latter is reached when the number of occupied ED beds is exceeding 120% of maximal capacity or if more than 20% of admitted patients are waiting for a bed on the hospital wards over a six-hour period. (https://publications.msss.gouv.qc.ca/msss/fichiers/2006/06-905-01.pdf)
- **Heavy clinical load:** The ISS sessions will be cancelled if the senior doctor determines that real ED patients are too complex and/or when the charge nurse observes that the ED staff is overwhelmed. To avoid the subjectivity of this "no go" parameter, we will use a scale of 0-10 where less than 5 is light workload, 5 is regular workload and 10 is a very heavy workload with which staff feels overwhelmed. If the charge nurse selects 7 or more, we will cancel ISS.
- **Equipment needs** (i.e., unavailability of the fast flow fluid warmer).
- **If a real trauma activation is expected or ongoing**
- **Unanticipated Events/Threats to Psychological Safety[1] and Physical Safety** (i.e., a terrorist attack, a mass casualty alert (code orange), fire, flood, or any violent threats (code silver)).

Online Supplementary material – Information sheet for participants

Feuillet d'information
Titre de l'étude : In Situ
Impact et acceptabilité de la simulation in situ aux urgences

Version approuvée par le CER du CHU de Québec-Université Laval le 23 janvier 2020
2020-5030

Chercheur principal local : Dr Marcel Emond

Préambule

Le Service de l'urgence de l'Hôpital de l'Enfant-Jésus du CHU de Québec-Université Laval mène une étude portant sur la simulation in situ comme nouvel outil pédagogique à l'urgence. Nous souhaitons recueillir les commentaires de médecins, infirmières, préposés, inhalothérapeutes et résidents dans le but d'améliorer le développement de ces formations.

Nous sollicitons votre participation à ce projet de recherche puisque vous travaillez dans le service de l'urgence de l'Hôpital de l'Enfant-Jésus du CHU de Québec-Université Laval. Cependant, avant d'accepter de participer à ce projet, veuillez prendre le temps de lire, de comprendre et de considérer attentivement les renseignements qui suivent. Nous vous invitons à poser toutes les questions que vous jugerez utiles au chercheur responsable de ce projet ou à un membre de son personnel de recherche et à leur demander de vous expliquer toute information qui n'est pas claire.

Nature et objectif de l'étude

Cette étude vise à améliorer la formation des professionnels de la santé de l'urgence et améliorer la qualité de vie au travail. L'objectif principal de ce projet consiste à évaluer la faisabilité et l'acceptabilité de mise en place de simulations in situ au Département d'urgence. Suite à ces simulations, nous tenterons d'évaluer si une diminution du stress et une augmentation de la confiance en soi peuvent être observées.

Déroulement du projet de recherche

Suite aux simulations, nous vous demanderons de participer à une entrevue enregistrée qui durera environ 45 minutes. Les entrevues auront lieu soit en personne, par téléphone ou via Skype/Zoom, avec un membre de l'équipe de recherche. Cette entrevue vous permettra de nous faire part de vos expériences lors de séances de simulation in situ à l'urgence. L'information que vous fournirez servira uniquement aux fins de cette étude. Certaines des questions seront de nature personnelle. Vous aurez l'option de ne pas répondre à toute question qui vous rendrait mal à l'aise.

Nous vous demanderons également de compléter à un questionnaire dont les réponses seront anonymisées. Ce questionnaire devrait prendre environ 15 minutes de votre temps.

Toutes les séances de simulation sont confidentielles et dans l'objectif unique d'améliorer les compétences techniques et non techniques. Il ne s'agit en aucun cas d'une évaluation.

Feuillet d'information
Titre de l'étude : In Situ
Impact et acceptabilité de la simulation in situ aux urgences

Participation volontaire et possibilité de retrait

Votre participation à ce projet de recherche est volontaire. Vous êtes donc libre de refuser d'y participer. Vous pouvez également vous retirer de ce projet à n'importe quel moment, sans avoir à donner de raisons, en informant l'équipe de recherche.

La décision de ne pas participer à ce projet de recherche ou de vous en retirer n'aura aucune conséquence sur votre emploi ou sur votre relation avec vos collègues.

Risques et inconvénients associés au projet de recherche

Vous pourriez être mal à l'aise lorsque vous discutez de vos expériences. Vous pouvez choisir de ne pas répondre aux questions ou de mettre fin à l'entrevue à tout moment si vous ressentez un inconfort. Outre le temps consacré à l'entrevue, aucun autre inconvénient associé à votre participation à cette étude n'est connu.

Avantages associés au projet de recherche

Il est possible que vous ne retiriez aucun avantage direct en prenant part à cette étude. Nous espérons que les renseignements obtenus lors de cette étude permettront d'aider les professionnels de la santé de l'urgence en démontrant que ce format nouveau de formation est faisable, acceptable et même bénéfique à la fois pour les professionnels de l'urgence mais aussi pour augmenter la sécurité des patients.

Confidentialité

Durant votre participation à ce projet, le chercheur responsable ainsi que son personnel recueilleront et consigneront dans un dossier de recherche les renseignements vous concernant. Seuls les renseignements nécessaires pour répondre aux objectifs scientifiques de ce projet seront recueillis. Tous les renseignements recueillis demeureront confidentiels dans les limites prévues par la loi. Afin de préserver votre identité et la confidentialité de vos renseignements, ce dernier sera identifié que par un numéro de code. La clé du code reliant votre nom à votre dossier de recherche sera conservée par l'équipe de recherche.

Le personnel de l'étude pourrait communiquer avec vous par courriel afin de prévoir un rendez-vous pour l'entrevue. La communication par courrier électronique n'est pas entièrement sécuritaire. Il est déconseillé de communiquer des renseignements personnels sensibles par courrier électronique.

Au cours des entrevues, les participants devront s'abstenir de nommer les personnes par leurs noms. Si des noms ou d'autres renseignements identifiants devaient être partagés pendant la discussion, ceux-ci ne seront pas inclus dans les transcriptions. Les enregistrements audio seront stockés en lieu sûr et seuls des membres de l'équipe de recherche pourront y avoir accès. Les enregistrements seront conservés jusqu'à ce qu'ils aient été transcrits (rédigés sous forme écrite), après quoi ils seront détruits. Les transcriptions seront conservées pendant une période de 10 ans.

Vos données anonymisées découlant de cette étude serviront uniquement à des fins de recherche. Les données de recherche pourront être publiées ou faire l'objet de discussions scientifiques, mais il ne sera pas possible de vous identifier.

À des fins de surveillance, de contrôle, de protection et de sécurité, votre dossier de recherche pourra être consulté par des représentants de l'établissement ou du comité d'éthique de la recherche. Ces personnes adhèrent à une politique de confidentialité.

Vous avez le droit d'être informé des résultats de cette étude une fois terminée. Si vous désirez être informé des résultats de cette étude, ou consulter votre dossier de recherche veuillez en informer l'équipe de recherche.

Compensation

La participation aux formations sera rémunérée comme temps de travail et accrédité pour la formation continue.

Indemnisation en cas de préjudice et droits du participant à la recherche

En acceptant de participer à ce projet, vous ne renoncez à aucun de vos droits ni ne libérez le chercheur responsable de ce projet de leur responsabilité civile et professionnelle.

Identification des personnes-ressources

Si vous avez des questions ou éprouvez des problèmes en lien avec le projet de recherche, ou si vous souhaitez vous en retirer, vous pouvez communiquer avec le médecin responsable ou avec une personne de l'équipe de recherche au numéro suivant : (418) 649-0252, poste 66423.

Si vous avez des commentaires ou des questions à poser concernant vos droits en tant que participant à la recherche, ou si vous avez des plaintes ou des commentaires à formuler, vous pouvez communiquer avec la Commissaire locale aux plaintes et à la qualité des services du CHU de Québec – Université Laval au (418) 654-2211.

Surveillance des aspects éthiques du projet de recherche

Le comité d'éthique de la recherche du CHU de Québec-Université Laval a évalué la conformité du projet 2020-5000-aux principes qui gouvernent l'éthique de la recherche, et il en assurera le suivi.

En prenant part à cette entrevue, votre consentement à la participation à cette étude de recherche est implicite.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___N/A_____
	2b	All items from the World Health Organization Trial Registration Data Set	____ N/A _____
Protocol version	3	Date and version identifier	_____2_____
Funding	4	Sources and types of financial, material, and other support	_____1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1_____
	5b	Name and contact information for the trial sponsor	_____1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____1-2_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____ N/A _____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-7-8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figures

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_____14_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____N/A_____

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____ N/A _____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	____ N/A _____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____ N/A _____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____ N/A _____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___ N/A _____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_11-12-13-14-15_
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____ N/A ____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___11_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	____14-15_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	____N/A___
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	__ N/A _____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____N/A____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____ N/A ____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	____N/A_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____N/A____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___3_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____3____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____11_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____1-2_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	____ N/A ____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____ N/A _____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____17_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____ N/A ____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____ N/A ____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_ Online supplentary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	__ N/A _____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.